EFFECTIVENESS OF POVIDONE IODINE DRESSING VERSUS NORMAL SALINE DRESSIING ON WOUND HEALING AMONG PATIENT WITH DIABETIC FOOT ULCER AT GOVERNMENT RAJAJI HOSPITAL, MADURAI

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THE TAMILNADU Dr. M.G.R. MEDICAL UNIVERSITY

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In partial fulfillment of the requirement for the degree of

MASTER OF SCIENCE IN NURSINIG

OCTOBER - 2017

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"COMMIT TO THE LORD WHATEVER YOU DO, AND HE WILL ESTABLISH YOUR PLANS"

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ABSTRACT

Title: Effectiveness of povidone iodine dressing versus normal saline dressing on wound healing among patients with diabetic foot ulcer at Government Rajaji Hospital, Madurai. **Objectives:** To compare the effectiveness between Povidone iodine dressing (Group I) and Normal saline dressing (Group II) on wound healing among patients with diabetic foot ulcer. **Hypothesis:** There is a significant difference between the post test level of wound healing among patients with diabetic foot ulcer in Group I, Group II. There is a significant association between the level of wound healing among Group I, Group II patients with diabetic foot ulcer at Government Rajaji Hospital with their selected socio demographic and clinical variables. **Conceptual framework:** Modified Hildegard E. Peplau Theory of Interpersonal Relations. **Methodology:** Quantitative approach – True experimental study – Pretest Post test design. Sample size was 60 selected by consecutive sampling technique. Randomly assigning the samples for experimental group I and experimental group II. Pretest was done on the first day using PEDIS classification and Scoring system and diabetic foot ulcer wound was graded. Patients in the experimental group I received Povidone iodine dressing and experimental group II received normal saline dressing every morning, once a day for 6 consecutive days. Post test was conducted on 7^{th} day using PEDIS classification and scoring system for both groups. **Findings:** the findings revealed that there was a significant improvement in level of diabetic foot ulcer wound healing after the intervention, which was confirmed by Student's independent t – test value $t = 12.45$ & $t = 6.41$ respectively and $p = \leq 0.05$ level of significance. **Conclusion:** The statistical evidence proved that the povidone iodine dressing and normal saline dressing was effective in improving the wound healing among group I and group II patients with diabetic foot ulcer. When comparing the level of diabetic foot ulcer wound healing between group I and group II it was proved that povidone iodine dressing was more effective than normal saline dressing.

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INTRODUCTION

CHAPTER - I

INTRODUCTION

"The human foot is a masterpiece of engineering and a work of art."

Leonardo da Vinci

Health is real wealth. A healthy person is an asset to himself, to his family and to his community. On the other hand an ailing person is a burden on all. He is a danger for coming generations because heredity plays an important part in this respect. Health is the pivot upon which a man's whole personality and its well-being depend. An ailing and aching body saps the enthusiasm for pursuit. Unwholesome feelings and sensations retard the pace of functional activity, economic development and spiritual uplift.

Good health is a possible gift of nature to man and he must give a return gift to nature by preserving and enhancing his health potential in line with various natural situations. Health is the most precious possession of an individual and one must take optimal care of it. The best way to maintain good health is to be on guard against any alarming, unusual changes that one may experience. This entails regular medical check up at given interval so that one is kept free of disease and/or deformity.

A disease or disorder is a condition that impairs the proper function of the body or of one of its parts. Every living thing, both plants and animals, can succumb to disease. Hundreds of different diseases and disorders exist. Each has its own particular set of symptoms and signs, clues that enable a physician to diagnose the problem. A symptom is something a patient can detect, such as fever, bleeding, or pain. A sign is something a doctor can detect, such as a swollen blood vessel or an enlarged internal body organ. Every disease has a cause, although the accuses of some

remain to be discovered. Every disease also displays a cycle of onset, or beginning, course, or time span of affection, and end, when it disappears or it partially disables or kills its victim.

Non communicable diseases (NCDs) contribute to around 5.87 million deaths that account for 60 % of all deaths in India. India shares more than two-third of the total deaths due to NCDs in the South-East Asia Region (SEAR) of WHO. Four types of NCDs —cardiovascular diseases, cancer, chronic respiratory diseases and diabetes make the largest contribution to morbidity and mortality due to NCDs. Four behavioural risk factors are responsible for significant proportions of these diseases—tobacco use, unhealthy diet, physical inactivity and harmful use of alcohol.

Diabetes mellitus is a group of metabolic disorders characterized by elevated levels of glucose in the blood (hyperglycemia) resulting from defects in insulin secretion, insulin action or both. Diabetes is an ice berg disease according to 2016 estimation the prevalence of diabetes mellitus in adult was around 4th worldwide and this means that over 150 million persons now affected

Diabetes mellitus has been known for centuries, although it has not been fully understood. The ancients first described diabetes, the cardinal features of a polyuric state were described in an Egyptian papyrus, “Ebers papyrus” dating from c. 1550 BCE. . Aretaeus of Cappadocia, a Greek physician in the 2nd century, was the first to use the term “diabetes.” He gave the first complete clinical description of the disease when he described symptoms as immense thirst, “the melting down of flesh and limbs into urine”, and short survival.

The word diabetes stems from the Greek word for siphon, “diabaino”, which also means “to go or run through” alluding to the incessant flow of urine through the

body. The first written documentation of the sweetness of diabetic urine occurs in a Hindu document dated 400-500 BCE. In 1675 professor Thomas Willis at Oxford rediscovered the sweetness of urine, the taste of sugar or honey, and wrote the treatise entitled “Diabetes, or the pissing evil”. In 1776 the physician Matthew Dobson in Liverpool published the first description of hyperglycaemia. He found that both the serum and the urine from one of his patients tasted sweet. The Scottish physician John Rollo created the first medical diet to treat diabetes consisting of rancid meat, blood pudding and a mixture of milk and limewater. He also added the term “mellitus” (the Greek word for honey) to “diabetes” in order to distinguish it from diabetes insipidus. Paul Langerhans, a German medical student, discovered in 1869 the islet cells of the pancreas but was unable to explain the nature and function of these cells. Later on these cells were named ‘islets of Langerhans.

According to the report of World Health Organization (WHO) the number of diabetic patients in 2000 reached to 171 million and was predicted to increase 380 million by 2025. So, at now in most countries diabetes is becoming as an epidemic disorder. There exist evidence demonstrating the significant consequences of the disease on both health care providers and the community as a whole. Solving this problem requires close collaboration among health system and people; develop national and international strategies and interaction with other health team members. By this approach, providing adequate and effective health services are necessary for patients and their families Also, improving the quality of nurses’ clinical performance can lead to changes in client and patient societies

Diabetes is a very serious disease can lead to microvascular and macrovascular complications. If left unchecked, it can bring serious consequences including death. Fortunately, it is a disease that can be managed but same time most

of the people who have diabetes do not know that they have it and hence do not treat it till it becomes very late. People with diabetes are more likely to have foot problems because of nerve and blood vessel damage. Small sores or breaks in the skin may turn into deep skin ulcers if not maintained normal blood sugar level it may go for gangrene. If these skin ulcers do heal properly, or become larger or go deeper, in this stage the patient may need an amputation of the affected limb.

Foot problems constitute the primary cause of hospitalization of people with diabetes. Above 15% develops foot or leg ulcer. Amputation is common between 1994 and 1996 the number of diabetes related amputation who have had one amputation have 28% to 51% chance of needing a centralized one within five year. Overall, the rate of lower limb amputation in diabetic patients is 10–30 times higher than non diabetics. The studies showed that every 30 seconds one leg is amputated due to diabetes in the world. In the first two years after amputation, there is a 50 percent risk of re-amputation and three years after lower limb amputation, 50% of patients may be dead.

The primary steps in the treatment of diabetes foot ulcer is wound closure elevation of the affected foot and relief of pressure are essential component of treatment and should be initiated at first presentation ill fitting foot wear should be replaced with a post operative shoe or another type of pressure reliving foot wear

Foot problems in diabetic patients account for more hospital admissions than any other long-term complications of diabetes and also result in increasing morbidity and mortality. The diabetic foot syndrome encompasses a number of pathologies, including diabetic neuropathy, peripheral vascular disease, Charcot neuroarthropathy, foot ulceration, osteomyelitis, and the potentially preventable end point amputation.

Patients with the diabetic foot can also have multiple diabetic complications and caring for such patients may require attention to many different areas.

Globally, diabetic foot infections are the most common skeletal and soft-tissue infections in patients with diabetes. The incidence of diabetic foot infections is similar to that of diabetes in various ethnic groups and most frequently affect elderly patients. There are no significant differences between the sexes. Mortality is not common, except in unusual circumstances. Diabetes affects approximately 170 million people worldwide and by 2030 these numbers are projected to double. 10 The foot ulcer is a leading cause of hospital admissions for people with diabetes in the developed world and is a major morbidity associated with diabetes11, often leading to pain, suffering, and a poor quality of life for patients. Diabetic foot ulcers (DFUs) are estimated to occur in 15% of all patients with diabetes11 and precede 84% of all diabetes related lower-leg amputations.

The development of diabetic foot ulcers results from several factors. These factors can increase the risk of foot ulcer and cause detachment in the skin or impairment in the wound healing. Peripheral neuropathy can cause excessive pressure on some points of the feet and consequently, ischemia can increase the susceptibility to ulceration by impairment in peripheral vascular. In addition, other factors such as poor vision, limited joint movement, inadequate foot coverage and shoes can be susceptive to ulceration in diabetics. The most important point is that 85% of diabetic foot amputations are preventable with appropriate care and education. Ideal management for prevention and treatment of diabetic foot is as follow: regular perception of foot, determine at risk foot, education to patient and health staff, appropriate foot coverage, and early treatment of foot problems.

The World Health Organization (WHO) has projected that the maximum increase in diabetes would occur in India. Considering the large population and the high prevalence of diabetes, the burden of diabetes in India would become enormous. Diabetic foot infection is a common cause for the hospital admissions of the diabetic patients in India. This could be attributed to several sociocultural practices such as barefoot walking; inadequate facilities for diabetic care low education and poor socio-economic conditions.

India, with a population of more than 1.1 billion, has the dubious distinction of having a larger number of people with diabetes and there were no major difference in the risk factors when compared with developed countries, while the clinical features may vary in developing countries because of the regional factors. Role of Pathogens in diabetic foot infection in India.

In India, the prevalence of diabetic foot ulcers in clinical population was estimated to be 3.6%.3 Socio cultural practices such as bare-foot walking, use of improper foot wear and lack of knowledge regarding foot care contributes towards increase in prevalence of foot complications in India. Foot infection is the most common reason for hospitalization accounting to up to 25% of admissions. 15% of the patients develop foot ulcers during their lifetimes. If untreated they end in lower extremity amputation. Diabetic foot ulcers should be treated aggressively to improve the quality of life, control infections, maintain patient's health, prevent amputations and to reduce health care costs. Topical treatment is an important aspect of diabetic foot ulcers although secondary to surgical and systemic care.

In ancient Greek and Roman medicine, sea sponges were used to absorb fluid from wounds. These were also soaked in wine and used as an antibacterial wound dressing. In 1880s the dressing was made from gauze, cotton and coconut fiber, and

had a center capsule containing an antiseptic. Later these gauze, small pieces of which were impregnated with extracts of opium and lettuce seeds and inserted into wound cavity of patients as a device to induce wound healing. The first 'modern' dressings to be used in wound management and became widely available in the mid-1970s. The dressings are able to absorb exudate into the air spaces within the structure in a similar manner. Dressing absorbs the exudates by capillary action and it is held within the structure thereby removing the exudates and edema fluid and enhancing epithelialization.

Wound healing is a complex and dynamic process of restoring cellular structures and tissue layers. The human adult wound healing process can be divided into 3 distinct phases: the inflammatory phase, the proliferative phase, and the remodeling phase. Within these 3 broad phases is a complex and coordinated series of events that includes chemotaxis, phagocytosis, neocollagenesis, collagen degradation, and collagen remodeling. In addition, angiogenesis, epithelization, and the production of new glycosaminoglycans (GAGs) and proteoglycans are vital to the wound healing milieu. The culmination of these biological processes results in the replacement of normal skin structures with fibroblastic mediated scar tissue.

In choosing a dressing for an infected diabetic foot ulcer, several factors have to be taken into account. Infected wounds tend to have a heavy exudate that needs to be controlled to prevent maceration of surrounding tissue. There may be considerable odor associated with infection that may be unpleasant and distressing for the patient and family. A dressing must be comfortable and acceptable for the patient and should help alleviate or, at the very least, not worsen pain, especially at dressing changes. Ideally, the dressing should also aid in the management of the infection itself.

Antiseptics, such as iodine-based preparations, are commonly used on wounds, as they have high beneficial effect. Typically they are applied to locally infected wounds, usually in combination with systemic antibiotics. Iodine comes in 2 main preparations: cadexomer-iodine and povidone-iodine. Iodine is bactericidal in vitro, with maximal activity at 0.1%–1%. Povidone-iodine has long been used as a skin antiseptic, but its antimicrobial effect on wounds is debatable. A randomized controlled trial of iodine versus saline-soaked gauze on clean foot ulcers showed no significant difference in healing between the groups. Certain iodine dressings are highly absorbent and therefore useful in preventing skin excoriation in moderately exudating ulcers. In clinical practice, iodine are used for cavity wounds and povidone-iodine gauze for superficial ulcers, many studies consider iodine preparations to be appropriate dressings for infected diabetic foot ulcers

Normal saline is isotonic and the most commonly used wound care solution due to safety (lowest toxicity) and physiologic factors. It is also used as a irrigating solution to cleanse dirty, necrotic wounds as effectively as other solutions. Salt is a natural element that's been used for centuries to aid in healing, wounds and otherwise. The therapeutic uses have been recorded in both ancient Egyptian and Roman history. Hippocrates made medicines containing salt after realizing the reparative nature of seawater on fishermen's hands, and Renaissance doctors recommended salt baths for patients with skin diseases.

Diabetic foot ulcer (DFU) is a full-thickness wound, skin necrosis or gangrene below the ankle induced by peripheral neuropathy or peripheral arterial disease in patients with diabetes. It is one of the most common, severe and costly complications of diabetes and the most frequent cause for diabetes-associated hospitalization in India as well as the rest of the world. Because of diabetes-related delayed wound

healing, Diabetic foot ulcer may lead to lower limb amputation, which deteriorates patients' quality of life and increases mortality. Given these various negative impacts, it is crucial to define a standardized and efficient approach to treat Diabetic foot ulcer in a timely manner; the first step should be the correct identification of degree of risk for ulcer-related complications in all patients with Diabetic Foot Ulcer.

Many Diabetic foot ulcer classification systems have been proposed to predict clinical outcome; however, almost of these systems have limitations. First, the majority of the classification systems only focus on local pathology of DFU and fail to adequately assess all the important parameters related to ulcer healing. For example, the Wagner system exclusively assesses ulcer depth without co-morbidities such as ischemia and neuropathy. Second, few classification systems incorporate standardized definitions of ischemia, infection and systemic variables important to wound healing. Finally, few classification systems of Diabetic foot ulcer have been validated, and no classification has gained universal acceptance.

To categorize and define Diabetic foot ulcer objectively and facilitate communication between health-care providers, the International Working Group of the Diabetic Foot (IWGDF) developed the Perfusion, Extent, Depth, Infection and Sensation (PEDIS) classification system in which all Diabetic foot ulcer are classified according to five categories: perfusion, extent/size, depth/tissue loss, infection and sensation. These categories were considered to be the most relevant pathogenesis of the development of Diabetic foot ulcer. Moreover, each subcategory is defined according to strict criteria based upon objective techniques, which are applicable worldwide. A validated classification system of DFU may help clinicians in everyday assessment and management of patients as well as researchers in the development and assessment of new therapies.

1.1 Need for the Study

Diabetic Foot Ulcer represents a frequent occurrence in diabetic population and up to 15% of subjects may be expected to develop a foot ulcer at least one time in his / her life. Diabetic foot ulcer cause personal, social and economical problems and are serious risk factors for death. These ulcers can be broadly classified as neuropathic, vascular or mixed although the pathogenesis is much more complex. Biochemical, hygienic, structural deformity, dynamics, pressure, skeletal, nutritional, socio economic factors, reduced antibacterial activities, work place influence all concur to cause and maintain the ulcer.

It is estimated that in 2016 approximately 460 million people have diabetes – 8.3% of the world's population. Around 80% of these people live in developing countries. By 2030, the global estimate is expected to rise to over 552 million – 9.9 % of the adult population. Every 20 seconds a lower limb is lost to diabetes somewhere in the world.

Diabetes mellitus (DM) is one of the main problems in health systems and a global public health threat that has increased dramatically over the past 2 decades. According to epidemiological studies, the number of patients with DM increased from about 30 million cases in 1985, 177 million in 2000, 285 million in 2010, and estimated if the situation continues, more than 360 million people by 2030 will have DM.

Patients with diabetes mellitus are prone to multiple complications but higher incidence of patients end up with diabetic foot ulcer (DFU). Diabetic foot ulcer is a common complication of diabetes mellitus that has shown an increasing trend over previous decades. In total, it is estimated that 15% of patients with diabetes will suffer

from DFU during their lifetime. Although accurate figures are difficult to obtain for the prevalence of DFU, the prevalence of this complication ranges from 4%-27%

Diabetes along with its complications results in increasing morbidity, mortality and health expenditure as specialized care is required. Ulcers that occur on the dorsal part of toes or on the bony eminences of the foot are often not due to trauma, but due to poorly fitting shoes. Thus, preventive care with footwear is very important. The practice of inspection of foot and use of appropriate footwear is considered important in early detection and prevention of further complications`

In 2003, there were 189 million diabetes in the world; the projected figure for 2025 is 300 million. Independent WHO observes put the total no of diabetes at 177 million India tops the best of 10 countries followed by China. In south India professor Lefebvre said, the incidence of diabetes and impaired glucose increasing since 1984, about 3.2 million people die of diabetes across the world every years. It is also estimated that there are 30-33 million diabetes in India now and every 4^{th} diabetics in the world today is an India.

By 2025, there will be around 300 million diabetic patients worldwide according to a study conducted by the World Health Organization (WHO). In India, an estimation of 61.3 million diabetics are present, which is expected to cross 100 million by the year 2030. The prevalence of diabetic foot ulcer among diabetics in a rural Indian study was found to be 10.4%.

By 2030, it is estimated that more than 550 million people around the world will have diabetes. Approximately 25% of these diabetic patients will develop foot ulcers during their lifetime, which often require advanced diabetic wound treatment to

prevent complications. To help achieve the optimal healing environment and protect against problems.

Diabetic foot ulcer (DFU) is a wound penetrating through the deep vascular and collagenous (dermis) layers of the skin in diabetic patients as a result of diabetic risk factors like poor metabolic control, older age, prolonged diabetes, foot deformities, peripheral vasculopathy and poor knowledge of diabetes. The risk of the diabetic patients developing the complication is about 15% while 5% of them are present with history of foot ulceration. 60–80% of foot ulcers will heal, 10–15% of them will remain active, and 5–24% of them will lead to limb amputation within a period of 6–18 months after the evaluation.

India is the country with the most of the people with diabetes, with a current incidence of 50.8 million followed by chance with 43.2 million the Russian (9.6 million), Brazil (7.6 million), Germany (7.5 million) Pakistan (7.1 million), Japan (7.1 million), Indonesia (7 million) and Mexico (6.8 million). A Staggering 285 million people worldwide have diabetes. Diabetic foot ulcer are common established to affect 15% of all diabetic individual during their life time the prevalence of diabetic foot ulcer in clinical population is 3.6%. Diabetic foot ulcer precedes almost 85% of amputation.

Foot ulcer is one of the most common and dreadest complication of diabetes mellitus. This is also a frequent cause of hospitalization and disability. Most of the patients with diabetic foot ulcers living in developing countries present to healthcare facilities fairly late with advanced foot ulcers because of poor economic status, inadequate knowledge of self-care, sociocultural reasons and poor and inadequate diabetes healthcare.

Diabetic foot complications are contributing to both mortality and morbidity among the diabetic population leading to substantial physical, physiological and financial burden for the patients and community at large. It is estimated that 24.4% of the total health care expenditure among diabetic population is related to foot complications and the total cost of treating diabetic foot complications is relatively high.

The risk of ulceration and amputation among diabetic patients increases by two to four folds with the progression of age and duration of diabetes regardless of the type of diabetes. It has also been proven by many longitudinal epidemiological studies that among diabetic patients, the life time foot ulcer risk is about 25%, thereby accounting for two thirds of all non-traumatic amputations

Diabetic foot ulcer (DFU) is not only a patient problem but also a major health care concern throughout the world. Diabetic foot ulcer is one of the common and serious complications in diabetic patients. Treatment of infection in diabetic ulcer is difficult and expensive. Patients usually need to take long-term medications or become hospitalized for an extended period of time. It is estimated that usually 15-25% of diabetic patients develop DFU during their life-time. On the other hand, more than 70% of patients who have developed DFU, experience an exacerbation of the disease in the next 5 years. The ulcer usually appears in the same extremity or the extremity of the opposite side; at least a quarter of these ulcers do not heal.

In choosing a dressing for an infected diabetic foot ulcer, several factors have to be taken into account. Infected wounds tend to have a heavy exudate that needs to be controlled to prevent maceration of surrounding tissue. There may be considerable odor associated with infection that may be unpleasant and distressing for the patient and family. A dressing must be comfortable and acceptable for the patient and should

help alleviate or, at the very least, not worsen pain, especially at dressing changes. Ideally, the dressing should also aid in the management of the infection itself. Diabetes Mellitus (DM) is a major health problem all over the world. Globally, the number of people that have been diagnosed with diabetes has exploded in the past two decades. The two most common types of diabetes were insulin-dependent diabetes mellitus (IDDM) or (type 1) and non-insulin-dependent diabetes mellitus (NIDDM) or (type 2).

Proper wound care will reduce infection, remove dead tissue and stimulate wound healing, allow for the inspection of underlying tissue, help with secretion or wound drainage, and optimize a wound dressing's effectiveness. Choosing the optimal dressing for a diabetic wound is essential to successful wound healing**.** The proper wound dressing will help maintain a balanced moisture environment (not too wet or too dry) and allow the wound to drain and heal properly. The location of the wound will also be taken into consideration when choosing a dressing. While each wound needs to be assessed properly.

The science of wound care has advanced significantly over the past ten years. The old thought of "let the air get at it" is now known to be harmful to healing. We know that wounds and ulcers heal faster, with a lower risk of infection, if they are kept covered and moist. The use of povidone iodine, peroxide, are recommended. Appropriate wound management includes the use of dressings and topically-applied medications. These range from normal saline ulcer dressings, and skin substitutes that have been shown to be highly effective in healing foot ulcers.

Nurses combine science and art to provide health services and seek to meet physical, emotional, mental, social-cultural and spiritual patient needs. Since patients care is the first duty of nurses, so that they play an important role in the care of

diabetes in developed countries, and diabetes nursing is divided into several categories, including nurse practitioner, clinical nurse specialist, diabetes nurse, generalist nurse and each of them has clear duties. For example, nurse practitioner focuses on health promotion and disease prevention activities including patient education and caring.

It is obvious that with the increasing prevalence of diabetes and its complications, there is undeniable need to train nurse specialist in this field. The diabetic foot is so important to such an extent that was considered as one of the main objectives of the Healthy People 2010 to reduce the incidence of foot ulceration and amputation in diabetic patients. So it was targeted a 55% reduction in amputations and an increase of nearly 75% in diabetic foot examinations and proper wound care.

Selection of dressing material and solutions used for dressing is also a key factor in diabetic wound healing, Wound dressing and irrigation is imperative to wound care because it creates an environment optimal for healing. Irrigation is done to remove debris or necrotic tissue, to clean the wound and to make it easier for your clinician to examine it. Saline water is water that contains dissolved salts. Using sterile saline water to irrigate wounds is one of the most common cleansing methods used by hospitals because it's a nontoxic isotonic solution. According to The Journal of Athletic Training, it's gentle enough to not damage healing tissues and neither adds nor takes fluid from the wound bed. There's no issue of possible allergies to this cleaning solution and it doesn't alter the bacterial flora responsible for repairing damaged skin.

Since the first discovery of the natural element iodine in 1811 by the chemist Bernard Courtois, iodine and its compounds have been broadly used for prevention of infection and treatment of wounds. However, molecular iodine can be very toxic for

tissues, so formulations composed by combination of iodine with a carrier that decreases iodine availability were developed. Povidone iodine (PVP-I) results from the combination of molecular iodine and polyvinyl pyrrolidone. Povidone iodine is available in several forms (solution, cream, ointment, scrub). Povidone iodine consists of spherical hydrophilic beads of cadexomer-starch, which contain iodine, is highly absorbent, and releases iodine slowly in the wound area. Numerous studies have been conducted in order to determine the safety and efficacy of iodine compounds on wound healing and proved that iodine is very effective indeed in reduction of infection and improving wound healing.

Government Rajaji Hospital, Madurai plays a pivotal role in caring the sick and deformed patients, its service rendered to the public is unexplainable. The hospitals extensive and equipped surgical wards are the example for the quality of care that is been provided to the public mainly patients with diabetic foot ulcer. In surgical wards of Government Rajaji Hospital, Madurai, monthly statistics of patients admitted with diabetic foot ulcer ranges from 40 – 60 patients. Annual statistics of the year 2016 was 386 patients with diabetic foot ulcer were admitted in surgical wards at Government Rajaji Hospital, Madurai.

The researcher during the clinical posting observed that the appropriate wound care is one of the essential components in managing diabetic foot ulcer. Along with the routine dressing maintaining moisture is also an important factor, use of Normal saline as an alternative dressing solution help in maintaining the moisture in the wound area and also act as an osmotic gradient in removing the exudates from the wound and low in toxicity thus improving the wound healing process. Hence the researcher was indented to evaluate the effectiveness of Povidone iodine dressing

versus Normal saline dressing on wound healing among patients with diabetic foot ulcer.

1.2 Statement of the Problem

"A study to evaluate the effectiveness of povidone iodine dressing versus normal saline dressing on wound healing among patients with diabetic foot ulcer at Government Rajaji Hospital, Madurai ".

1.3 Objectives

1. To assess the level of wound among Group I and Group II patients with diabetic foot ulcer at Government Rajaji Hospital, Madurai.
2. To evaluate the effectiveness of Povidone iodine Dressing among Group I and Normal Saline Dressing among Group II on wound healing among patients with diabetic foot ulcer at Government Rajaji Hospital, Madurai.
3. To compare the effectiveness between Povidone iodine dressing (Group I) and Normal saline dressing (Group II) on wound healing among patients with diabetic foot ulcer at Government Rajaji Hospital, Madurai.
4. To associate the level of wound among Group I, Group II patients with diabetic foot ulcer with their selected socio demographic and clinical variables.

1.4 Hypotheses

H_1: There is a significant difference between the pre test and post test scores among patients with diabetic foot ulcer in Group I, Group II at Government Rajaji Hospital, Madurai.

H_2: There is a significant difference between the post test level of wound healing among patients with diabetic foot ulcer in Group I (Povidone iodine), Group II (Normal Saline) at Government Rajaji Hospital, Madurai.

H_3: There is a significant association between the level of wound healing among Group I (Povidone iodine), Group II (Normal Saline) patients with diabetic foot ulcer at Government Rajaji Hospital with their selected socio demographic and clinical variables.

1.5 Operational Definition

Effectiveness

In this study the effectiveness refers to the desired result produced by Povidone iodine Dressing and Normal saline Dressing on wound healing among Patients with diabetic foot ulcer in Group I & Group II respectively and it will be measured using Modified Perfusion Extent Depth Infection Sensation - (PEDIS) Scoring system.

Povidone iodine dressing

In this study the Povidone iodine dressing refers to cleaning the diabetic foot ulcer with hydrogen peroxide, normal saline solution and application of povidone iodine impregnated dressing over the diabetic foot ulcer site once a day for 6 consecutive days.

Normal saline dressing

In this study Normal Saline dressing refers to cleaning the diabetic foot ulcer with hydrogen peroxide, normal saline solution and application of normal saline impregnated dressing over the diabetic foot ulcer site once a day for 6 consecutive days.

Wound healing

In this study wound healing refers to the restoration of structure of the damaged tissues, intactness of skin, absence of infection, maintenance of perfusion and sensation at the site of diabetic foot ulcer, it is measured using modified Perfusion Extent Depth Infection Sensation - (PEDIS) classification and scoring system.

Patients with diabetic foot ulcer

In this study Patients with diabetic foot ulcer refers to the adult patients who are diagnosed as diabetic foot ulcer and admitted in surgical wards at Government Rajaji Hospital, Madurai.

1.6 Assumptions

1. Patients with diabetic foot ulcer have poor wound healing.

1.7 Delimitations

1. The study is limited to patients with diabetic foot ulcer who are admitted in surgical wards at GRH, Madurai.
2. The study period is limited to 6 weeks

1.8 Projected Outcome

Povidone iodine Dressing and Normal Saline Dressing will help to improve wound healing in diabetic foot ulcer.

REVIEW OF LITERATURE

CHAPTER - II

REVIEW OF LITERATURE

"For the creation of a masterwork of literature two powers must concur, the power of the man and the power of the moment, and the man is not enough without the moment".

James Allen

Review of literature is a key step in research process. It refers to extensive exhaustive and systematic examinations of publications relevant to the research project. The researcher analysis existing knowledge before dealing into a new area of study, when interpreting the results of the study, and when making judgments about applications at a new knowledge in nursing practice

This chapter deals with two parts

Part – I: Review of literature related to studies**.**

Part – II: Conceptual framework

PART – I

The related literature is organized and presented under the following headings**.**

Section I: Literature review related to diabetic foot ulcer among patients with diabetes mellitus

Section II: Literature review related to effect of povidone iodine dressing on diabetic foot ulcer

Section III: Literature review related to effect of normal saline dressing on diabetic foot ulcer

Section IV: Literature review related to effect of Povidone iodine dressing versus Normal saline dressing on diabetic foot ulcer.

2.1 Literature review related to Diabetic Foot Ulcer among Patients with Diabetes Mellitus

Dr. Vinu Gopinath, S. Soundara Rajan (2016) conducted a cross sectional study on diabetes mellitus among diabetic foot ulcer patients in a tertiary care centre at Department of General Surgery, Sree Mookambika Institute of Medical Science, Kulase kharam, Tamilnadu, India, 100 patients with diabetic foot ulcer attending surgical outpatient department were enrolled using purposive sampling, the study revealed that 70.6% of people are not aware that diabetes is the cause for poor ulcer healing, 51% of people are aware of the complications of diabetes mellitus and 84.3% of people know the symptoms of diabetes mellitus.

E J Boyko, J H Ahroni, V Stensel, R C Forsberg, (2013) conducted a prospective study of risk factors for diabetic foot ulcer at Department of Medicine, University of Washington, Seattle, USA._749 diabetic veterans were enrolled, the study showed that past history of amputation 2.8%, previous foot ulcer 1.6 %, insulin use 1.6 %, Charcot deformity 3.5%, 15 mmHg higher dorsal foot transcutaneous PO2 0.8% 20 kg higher body weight than the normal 1.2 % , poor vision 1.9 % Certain foot deformities, reduced skin oxygenation and foot perfusion, poor vision, greater body mass, and both sensory and autonomic neuropathy independently influence foot ulcer risk for diabetic foot ulceration.

Pradeepa R et al. (2012) conducted a cross - section population - based study on prevalence and risk factors of diabetic neuropathy in south Indian type 2 diabetic subjects at urban and rural areas of Chennai. A total of 1629 diabetic subjects were randomly selected, diabetic neuropathy was assessed by vibratory perception using biothesiometry, the study revealed that the prevalence of neuropathy was significantly

higher (27.8%) in known diabetic subjects and (19.5%) in newly diagnosed diabetic subjects.

David J Margolis, MD, Ph.D., Scot Malay, DPM, (2011) conducted a retrospective study at Ankle and Foot Medical Centers of the Delaware Valley on Incidence of diabetic foot ulcer and lower extremity amputation among diabetic clients, 580 cases were studied and found that lower extremity amputations is 15 times greater in those with diabetes than with any other concomitant medical illness. It has been reported that annually, about 1 to 4 percent of those with diabetes develop a foot ulcer; 10 to 15 % of those with diabetes will have at least one foot ulcer during their lifetime.

Bergen (2010) conducted a survey to determine the history and factors associated with diabetic foot ulcer among people with diabetes mellitus in Norway, 1494 subjects were non randomly enrolled, the study showed that the overall proportion with a history of foot ulcer was 10.4%, age > or =75 years (1.8 %), height of men>175 cm (19 %), women>161 cm (13%), and macrovascular complications (2.6%).

Caroline A. Abbott (2009) conducted a descriptive study to determine foot ulcer rate and the contribution of neuropathy in United Kingdom. 15,692 diabetic patients in the community health care setting were screened for foot ulcers, foot deformities, neuropathy, and peripheral arterial disease. The study showed that 13,409 patients had any one of the foot complications as result of poor glycemic control, 23% had foot ulcer, 15.52 % had peripheral arterial disease, 61.48 % had neuropathy.

Christoph (2007) conducted a survey approach study to find out the incidence of amputations and their relative risks in diabetic foot ulcer patients at University

Diabetes Center, College of Medicine, King Saud University, Riyadh, Saudi Arabia. The study reports were compared to the non-diabetic population. The samples were selected from hospitals of approximately 160, 000 inhabitants. The result indicated that the incidence of amputations was 33.8% in diabetic foot ulcer population and 9.4% in non-diabetic population.

2.2 Literature review Related to Effect of Povidone Iodine Dressing on Diabetic Foot Ulcer

A Shukrimi. M. Med Ortho, A R Sulaiman. M. Med Ortho (2014), conducted a prospective study to know the effect of Povidone Iodine dressing for Wagner's grade-II diabetic foot ulcers at school of medical sciences, University Sains, Malaysia, 30 patients with Wagner's grade – II ulcer between the age 31 to 65 years old were selected. The study revealed that application of 0. 5 % povidone iodine dressing daily for a week with wound debridement and appropriate antibiotics, proved to be effective in healing Wagner's grade-II diabetic foot ulcers.

Georgiade, et al., (2013) conducted an experimental study on frequency of application of povidone iodine on bacterial control in diabetic wounds at Center for Genetic Engineering and Biotechnology (CIGB), Havana, Cuba, 50 patients were selected, the study revealed that control of bacterial growth in diabetic wounds was effective by using povidone iodine (71.34%) and the control of bacterial growth showed a significant correlation to the frequency of povidone iodine dressing application.

Prof. Dr. J. Jasmine (2011) conducted a experimental study on Effectiveness of Betadine Dressing on Wound Healing Process at Indira Gandhi Govt. General Hospital and post graduate institute, Pondicherry, quantitative approach by Simple

random sampling technique was used to select the samples. 60 samples were selected, The major findings of the study shows that 50% of the patients are at the age group of 36- 50 years, Regarding gender, majority of the samples were males 96.% application of betadine dressing on diabetic wounds is highly effective with controlled glycaemic levels.

Burks R (2009) conducted an experimental study on Povidone-iodine solution in Diabetic foot ulcer wound treatment at Verdugo Hills Hospital, Glendale, Canada, 100 patients were involved in the study. Povidone iodine dressing including topical and systemic administration of antibiotics, and antiseptic agents such as hypochlorite (bleach) and hydrogen peroxide have been used. The wound healing was assessed by progress of the wound through the stages of healing (inflammatory, proliferative/reepithelializing, and remodeling) 54 % patients were having chronic foot ulcer. It was found that povidone-iodine solution along with antibiotics and antiseptics for treatment of wounds, especially the chronic wounds was beneficial.

Goldenheim PD, (2003) conducted an experimental study on an appraisal of povidone-iodine and wound healing in USA, 650 patients were enrolled, the study revealed that povidone-iodine formulations, have a broad antimicrobial spectrum, and have not been reported to develop bacterial resistance further it was concluded that povidone-iodine preparations ($p = 0.001^*$) do not have a deleterious effect on wound healing.

Kramer SA (1999) conducted an experimental study on Effect of povidone-iodine on wound healing at St John's Mercy Medical Center, USA among 480 subjects with diabetic foot ulcer, the study states that 82. 43% povidone-iodine was effective for cleansing, irrigating, and dressing wounds.

2.3 Literature review related to effect of normal saline dressing on diabetic foot ulcer

R. Lakshmi (2015) conducted a Randomized Controlled Trial on Effectiveness of Normal Saline Vs Tap water in Irrigation of Chronic diabetic foot ulcer wounds in surgical OPD of All India institute Of Medical Sciences Hospital, 60 subjects were enrolled for the study, 30 subjects in Tap Water group, 30 subjects in Normal saline group. Subjects were randomly allocated to have the wound irrigated with either normal saline or tap water. The healing rate was assessed by percentage decrease in area at 2 weekly intervals. At the end of the 5-6 weeks follow up the percentage decrease in saline group was 45.34% (mean size: 8.42±6.57) compared to 40.58 % (mean size of 5.36±7.89) in tap water group. The study showed that there was significant difference between the wounds in term of wound infection and healing rate. Normal saline irrigation on chronic wounds has improvised effects.

Erik Nathan Hansen, (2013) conducted an experimental study on normal saline dressing in diabetic foot ulcer wound along with systemic antibiotic and topical antimicrobial agents, 60 patients were randomly assigned, it was found that normal saline is effective ($p = 0.009^*$) in wound healing when combined with multidimensional approach to diabetic foot ulcer.

J. K. Lim, L. Saliba, M. J. Smith, J (2011) conducted an experimental study on Normal saline wound dressing in wound management at Department of Plastic and Reconstructive Surgery, Westmead Hospital, Westmead, New South Wales, Australia, 20 subjects were involved in the study. It was proved that normal saline dressing was effective ($p = 0.001^*$) in wound management for maximum efficacy the dressing should be changed regularly.

Leung BK, Barbera LA, Carroll CA, (2010) conducted an experimental study on effects of normal saline instillation in conjunction with negative pressure wound therapy on wound healing, 100 subjects were involved, 4 cycles of normal saline instillation per day, the study showed that instillation therapy with normal saline lead to wound fill with higher quality granulation tissue (p = 0.004*) composed of increased collagen leading to faster wound healing.

Angeras MH, Brandberg A, Falk A, and Seeman T. (2010) conducted a randomized comparative study on effect of sterile saline and tap water for the cleaning of diabetic wounds at surgical outpatient department, European city hospital, London, 705 consecutive patient with diabetic wounds were selected, study showed that the infection rate in wounds cleaned with sterile saline was 5.4% compared with 10.3% in wounds cleaned with tap water. Hence tap water should be replaced by sterile saline for the cleaning of diabetic wounds.

2.4 Literature review related to effect of povidone iodine dressing versus normal saline dressing on diabetic foot ulcer

Ellikunnel Vithon Gopi, Amrut H. Basava, Siddharth Matad (2016) conducted a prospective study to compare the effectiveness of saline dressing versus povidone iodine dressing in chronic diabetic wound healing at surgery outpatient department and casualty of Government Medical College and Hospital, Kozhikode, Kerala, India**,** 40 patients were selected using consecutive sampling technique, the study shows that 3 out of 20 subjects in Saline treated group achieved complete healing by 6 weeks as compared to 1 out of 20 subjects in Povidone iodine treated group. There was a significant decrease in the wound surface area at 6^{th} week in Saline dressing group in comparison to the povidone iodine group at P = 0.03 (<0.05)

level of significance. Saline dressing is more effective in achieving healing in chronic diabetic wounds as compared to Povidone iodine dressing.

Romil Parikh, Girish Bakhshi, Madhushree Naik (2016) conducted a block-randomized, double blind, parallel-arm, study on The Efficacy and Safety of povidone iodine in Comparison with saline Solution in Wound Healing, 150 patients with were randomized into the two treatment arms. Patients were observed for eight weeks with weekly assessments. The study results showed that both agents are efficacious (p value 0.004*) but Saline yields healthy granulation tissue earlier and both agents appear to be safe for application.

Ahel K. Hammouri, MD (2015) conducted a comparative study on dressings with normal saline to povidone iodine in the management of diabetic foot ulcers in four district hospitals in Jordan, 200 patients with diabetic foot ulcers were allocated randomly to two groups. The study showed that introducing normal saline as a method of dressing reduced time of the healing, hospital stay and cost by 34%, 43%, 50%, respectively. The need for amputations was also reduced by 50%. The dressing material irritation and allergy were markedly reduced in comparison with povidone iodine.

Sudhir K Navadiya, Yagnesh L Vaghani, Mukesh P Patel (2013) conducted a comparative study on povidone iodine and saline dressing in various diabetic wounds in SMIMER, 60 cases of diabetic wound included after complete debridement of wound 30 cases were applied povidone iodine and rest 30 case were applied normal saline The study showed that total duration of treatment and hospital stay is less in povidone iodine in comparison to normal saline group (p value 0.001*). Use of povidone iodine increases a rate of wound healing due to bactericidal activity and patients have early recovery of average 7-10 days.

Shetty, Gautham J (2012) conducted a prospective, comparative study on conventional dressing (normal saline) versus povidone iodine dressing in non healing lower limb ulcers in A.J.SHETTY institute of medical science. 200 patients with non healing lower limb ulcers were included in the study, they were visually analysed at intervals of 7, 14 and 21 days for epithelialization, infection, exudation and biodegradation and response evaluated by scoring criteria. The results proved that in 88% of the cases there was complete epithelialization (p value 0.05*) in test group compared to control group which was 54%, povidone iodine is an effective dressing in full thickness skin wounds and acts as an efficient to prevent adhesions than the conventional dressing.

Prabusankar, P (2011) conducted a comparative study on efficacy of normal saline wound dressings versus povidone iodine wound dressings in chronic non healing non malignant foot ulcers in Surat Municipal Institute of Medical Education and Research (SMIMER), Surat, 60 patients were randomly divided into two groups The results showed that there was similar improvement in ulcer size in both the groups (p value = 0.001*), no complications seen in either of the group, reduction in size of ulcer in both the test group was similar.

Trina d souza, nita (2011) conducted a comparative study on role and side effects of topical saline dressing in diabetic ulcers with conventional dressing at selected hospitals in Bangalore, 100 patients with diabetic ulcer were randomly allocated into saline dressing and betadine dressing groups. Initial ulcer size and rate of granulation tissue formation was measured, twice daily dressing was done for 14 days for both groups. The study has shown better granulation tissue formation (t value 3.547, df=39), the mean rate of granulation tissue is 42.50%, negative bacterial

growth of 52% and decreased hospital stay 20.04 days in patients receiving betadine dressing than patients receiving saline dressing.

2.5 Conceptual Frame Work

Theories are systematic explanation of events in which constructs and concepts are identified, relationships are proposed and prediction are made to describe, explain, predict, prescribe, practice and research. A conceptual frame work is a set of prepositions that spells out relationships between them. Conceptual frame work plays several interrelated roles in progress of science their overall purpose is to make scientific findings meaningful and generalizable.

The conceptual frame work used for this study is based on Peplau's Interpersonal Relations Theory. Hildegard E. Peplau was born on September 1st, 1909, in Reading, Pennsylvania. She graduated from Pottstown, Pennsylvania, Hospital School of Nursing in 1931. She received BA in Interpersonal psychology from Bennigton College, Vermonr, in 1943, an MA, in psychiatric Nursing from Teachers College, Columbia, New York, in 1947, and Ed.D., in curriculum development from Columbia in 1953.

Peplau published her Theory of Interpersonal Relations in 1952. Peplau's theory explains the phases of interpersonal process, roles in nursing situations and methods for studying nursing as an interpersonal process. Nursing is therapeutic in that it is a healing art, assisting an individual who is sick or in need of health care.

Four sequential interpersonal relationships are Orientation, Identification, exploitation and resolution. Each of these phases' overlaps interrelates and varies in duration as the process evolves towards a solution.

Orientation Phase

During the orientation phase, the individual has a felt need and seek professional assistance. The nurse help the patient recognize and understand his problem and determine his need for help. In this study the orientation phase refers to the demographic variables such as age, gender, religion, marital status, mother tongue, educational qualification, dietary habit, personal habits, type of occupation, occupational environment, area of residence. and clinical variables such as type of diabetes, duration of diabetes mellitus, duration of diabetic foot ulcer, site of diabetic foot ulcer, adherence to treatment, type of anti-diabetic drugs, co-morbid conditions, BMI, random blood sugar level.

Identification Phase

In this phase, the patient responds selectively to people who can meet his or her needs. Each patient respond differently in this phase. The patient identifies with those who can help him or her and might actively seek out the nurse.

The response to the nurse are three folds

1. Participate with and interdependent with the nurse
2. Be autonomous and independent from the nurse
3. Be passive and dependent on the nurse

In this study identification phase refers to the pre test on level of diabetic foot ulcer wound in experiment group I and group II using Perfusion, Extent, Depth, Infection, Sensation (PEDIS) classification and scoring system.

Exploitation Phase

During exploitation phase, patient attempts to derive full value from what is offered to him through him through the relationship, new goals to be achieved through

personal efforts can be projected and power shifts from the nurse to patient as the patient delays gratification to achieve the newly formed goals. The individual beings to feel as through he or she is integral part of the helping environment and begins to take control of the situation by extracting help from the service offered. Throughout this phase, the patient works collaboratively with nurse to meet challenges and work towards maximum health. Thus in this phase the nurse aids the patient in using service s to help solve the final stage.

In this study exploitation phase refers to providing povidone iodine dressing to patients with diabetic foot ulcer in experimental group I and normal saline dressing to patients with diabetic foot ulcer in experimental group II

Resolution Phase

In this phase old goals are gradually put aside and new goals adopted. This is a process in which the patient frees himself from identification with the nurse. Because then patients needs have already been meet by the collaborative efforts between patient and nurse. During successful resolution, the patient drifts away from identifying with the helping person, the nurse patient become independent from the nurse as the nurse become independent from the patient. Resolution occurs only with the successful completion of the previous phases.

In this study resolution phase refers to the post test level of diabetic foot ulcer using Perfusion, Extent, Depth, Infection, Sensation (PEDIS) classification and scoring system.

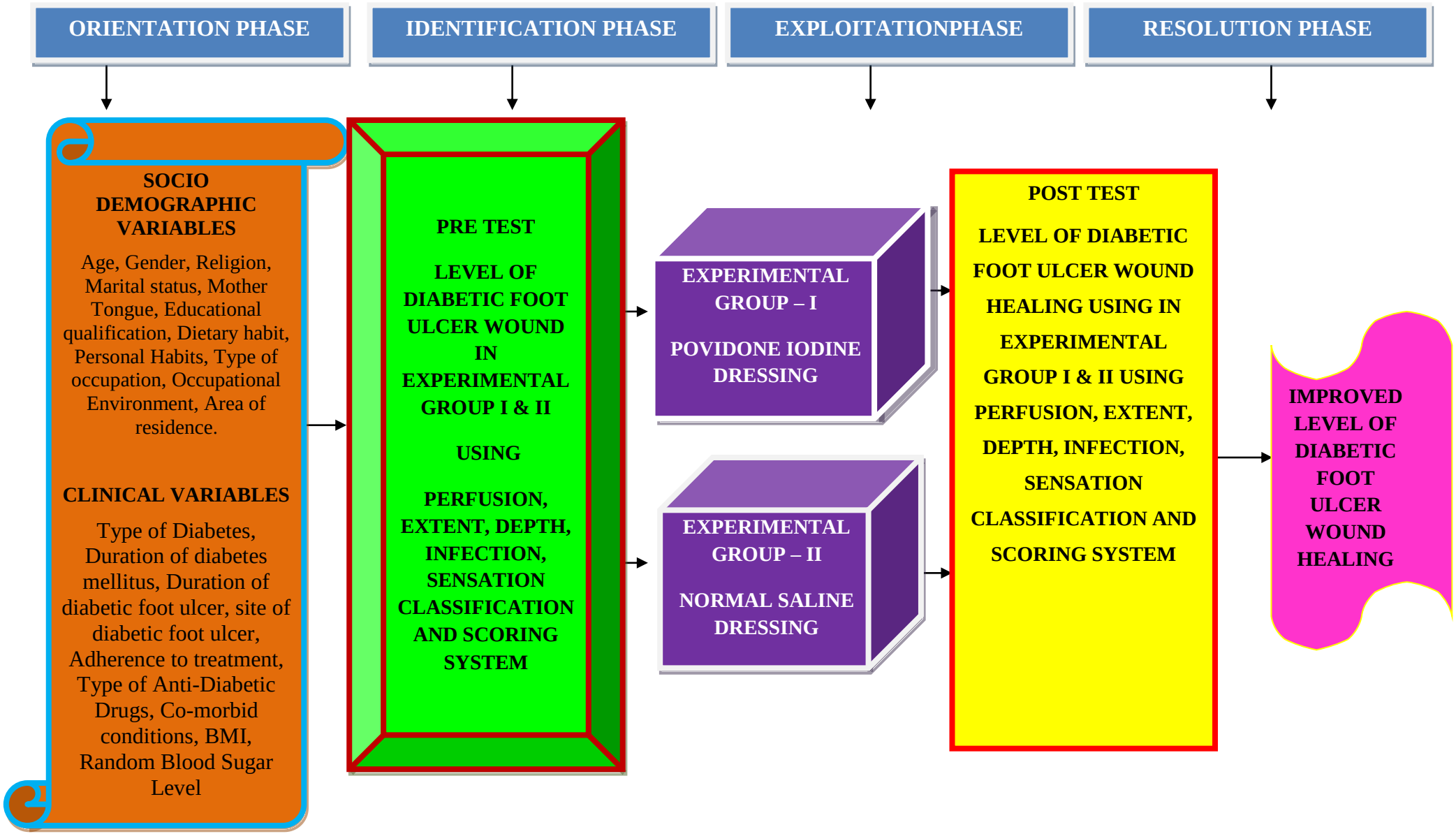


FIGURE: 1 MODIFIED HILDEGARD E. PEPLAU THEORY OF INTERPERSONAL RELATIONS

RESEARCH METHODOLGY

CHAPTER - III

RESEARCH METHODOLOGY

The methodology of research indicates the general pattern of organizing the procedure for assembling valid and reliable data for investigation. This chapter provides a brief explanation of the method adopted by the investigator in this study. It includes the research approach, research design, and variables, setting of study, population, sample, sample size, sampling technique, description of the tool, pilot study, data collection procedure and plan for data analysis.

The present study aimed to assess the effectiveness of povidone iodine versus normal saline dressing on wound healing among patients with diabetic foot ulcer at Medical wards, Government Rajaji Hospital, Madurai.

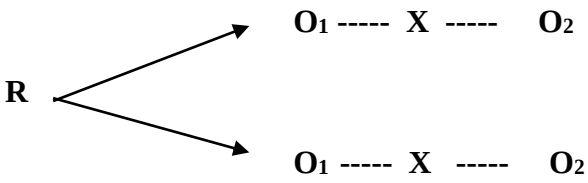
3.1 Research approach

The research approach is the most essential part of any research. The entire study is based on it. The study to assess the povidone iodine versus Normal Saline Dressing on wound healing among patients with diabetic foot ulcer was evaluated. Therefore a quantitative approach was used to assess the povidone iodine versus Normal Saline Dressing on wound healing.

3.2 Research design

Research design is the Researchers overall plan for obtaining answers to the research questions or for testing the research hypothesis.

The Researcher adopted True experimental- Pre test, Post test design for this study.



R-Random assignment

O_1 – Pre test for experimental group I and group II .

X - Intervention

O_2 – Post test for experimental group I and group II.

3.3 Research Variables

Independent variable – Povidone iodine and Normal Saline Dressing

Dependent Variable – Wound healing

Socio Demographic Variables – It includes Age, Gender, Religion, Marital status, Mother Tongue, Educational qualification, Dietary habit, Personal Habits, Type of Occupation, Occupational Environment, Area of residence.

Clinical Variable – Type of Diabetes, Duration of diabetes mellitus, duration of diabetic foot ulcer, site of diabetic foot ulcer, Adherence to treatment, Type of Anti-Diabetic Drugs, Co-morbid conditions, BMI, Random Blood Sugar Level

3.4 Research setting

The setting was selected based on acquaintance of the investigator with the institution, feasibility of conducting the study, availability of the sample, permission and proximity of the setting to investigation.

The study was conducted among patients with diabetic foot ulcer who are admitted in surgical wards at Government Rajaji Hospital, Madurai. At present there are about 3106 beds available in Multi Specialty Medical College attached hospital and it provides comprehensive care to all. Madurai Medical College is the second

largest in Tamil Nadu by man power and serving the poor people of whole south Tamil Nadu. Surgical wards consist of 250 beds and more then 35 – 40 patients with diabetic foot ulcer get admitted every month.

3.5 Population

Population is the entire universe of individuals, objects and events potentially available for research study.

Target population

The population in this study is the patient with diabetic foot ulcer.

Accessible population

Patients with diabetic foot ulcer, admitted in surgical wards at Government Rajaji Hospital, Madurai**.**

3.6 Sample

Patients diagnosed as diabetic foot ulcer and admitted in surgical wards at Government Rajaji Hospital, Madurai, who fulfills the inclusion criteria.

3.7 Sampling technique

Sampling technique used in the study was consecutive sampling technique, non probability sampling method.

3.8 Sample size

Sample size consists of 60 patients with diabetic foot ulcer. 30 Patients in Group I and 30 Patients in Group II

3.9 Criteria for Sample Selection

Inclusion criteria

1. Patients with Grade – I, II Diabetic Foot ulcer as per Modified Perfusion Extent Depth Infection Sensation - (PEDIS) Scoring system.
2. Who are willing to participate in the study

3. Patients who are fully conscious and oriented

Exclusion criteria

1. Patients who are contra indicated for Povidone iodine Dressing and normal saline dressing
2. Patient who are not available at the time of study

3.10 Description of the tool

With extensive review of literature and consultation with expert opinion the tool was selected to generate the data. The tool for data collection consist of two sections

- **Section A:** Socio demographic Variable and Clinical Variables
- **Section B:** Modified Perfusion Extent Depth Infection Sensation - (PEDIS) classification and scoring system.

SECTION A – Socio demographic variables and clinical variables

This section includes age, gender, religion, marital status, mother tongue, educational qualification, dietary habit, personal habits, type of occupation, occupational environment, area of residence. and clinical variables such as type of diabetes, duration of diabetes mellitus, duration of diabetic foot ulcer, site of diabetic foot ulcer, adherence to treatment, type of anti-diabetic drugs, co-morbid conditions, BMI, random blood sugar level.

SECTION B: Modified [Perfusion Extent Depth Infection Sensation - (PEDIS)] classification and scoring system

SCORING PROCEDURE

Section -A: There was no score allotted for socio demographic variables.

Section-B: Modified -Perfusion, Extent, Depth, Infection, Sensation (PEDIS) classification and scoring system for diabetic foot ulcer, scoring allotted as follows.

Testing of the Tool

3.11 Content Validity

The content validity of the tool with evaluation criteria checklist was submitted to five experts in the field of Medicine and Medical surgical Nursing for the opinion of the items in the tool. There was 100% agreement by the experts and minimal modification were made in socio demographic variables and clinical variables based on their suggestions.

3.12 Reliability

Modified Perfusion, Extent, Depth, Infection, Sensation classification and scoring system -this standardized scale reliability is r = 0.78. The Reliability of an instrument is the degree of consistency with which it measures the attribute and it is supposed to be measuring over a period of time. The tool was a standardized one which underwent test retest for reliability. Modified Perfusion, Extent, Depth, Infection, Sensation classification and scoring system has been administered on two different occasions and the Reliability has been estimated using the karl pearson's correlation coefficient formula, that is r = 0.78. Hence the tool is considered as reliable and used in this study.

3.13 Pilot study

A formal permission was obtained from ethics committee and surgical department Government Rajaji Hospital, Madurai. The pilot study was conducted at above department for a period of 7 days from 06/03/2017 to 12/03/2017. Informed consent was obtained from the participants. Samples were selected as per the inclusion criteria and randomly assigning the sample in to experimental group I and experimental group II in surgical ward. Pretest was done on the first day using PEDIS classification and scoring system and diabetic foot ulcer wound was graded. In which

the experimental group I receives Povidone iodine dressing and experimental group II receives Normal saline dressing, one times a day for 6 consecutive days and post test was done using the modified PEDIS classification and scoring system on the 7th day. The study was practically feasible to be conducted with a larger sample size.

3.14 Ethical Consideration

This study was conducted after the approval from the Ethics Committee Madurai Medical College, Madurai-20. All the respondents were carefully informed about the purpose of the study and their part during the study and how the privacy was guarded. Confidentially was ensured. Written permission was obtained from all participants.

3.15 Data collection procedure

After obtaining permission from ethics committee of Government Rajaji Hospital Madurai and HOD of department of surgery in Government Rajaji Hospital Madurai the data collection was done from 20/03/2017 to 30/04/2017. Rapport established with diabetic foot ulcer patients after brief introduction about the study and its purpose. The written and oral content was obtained from the patients after fully explaining the procedure of the study. On the first day of data collection the researcher selected samples as per the inclusion criteria. Randomly assigning the samples for experimental group I and experimental group II. Pretest was done on the first day using PEDIS classification and Scoring system and diabetic foot ulcer wound was graded. Patients in the experimental group I received Povidone iodine dressing and experimental group II received normal saline dressing every morning, duration of each dressing takes 15 to 20 minutes approximately, dressing is done once a day for 6 consecutive days. Post test was conducted at 7th day using PEDIS classification and

scoring system for both the groups. Sample procedure followed for 6 weeks until the fulfillment of required samples.

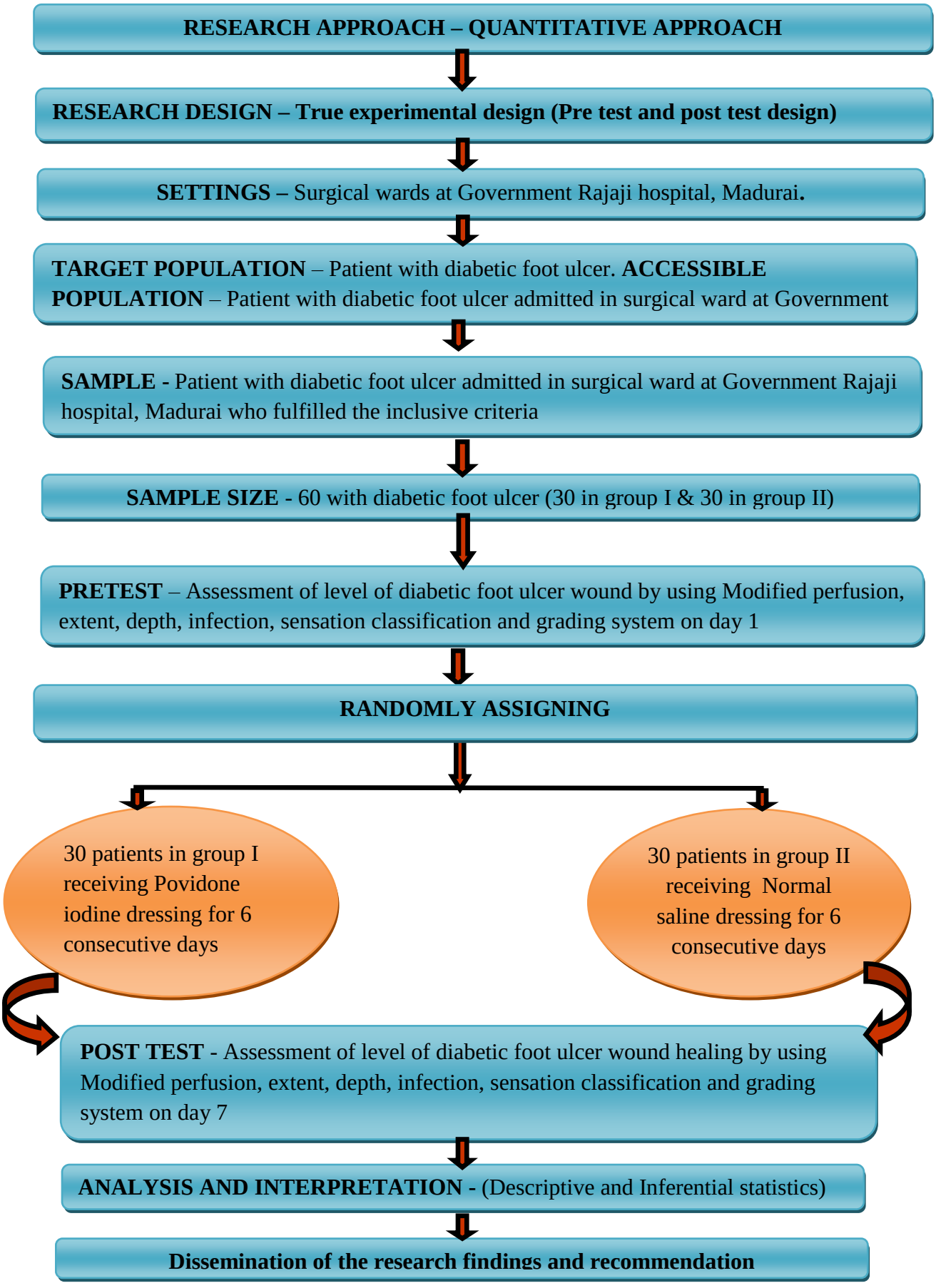
3.16 Plan for data analysis

The data analysis was done according to the objectives of the study. Both descriptive and inferential statistics were used. Socio demographic and clinical variables data were analyzed in frequency and percentage distribution. Mean and standard deviation were used to analyze the changes in the level of diabetic foot ulcer wound healing. Paired 't' test was used to evaluate the effectiveness of povidone iodine dressing among group I patients with diabetic foot ulcer and effectiveness of normal saline dressing among group II patients with diabetic foot ulcer. Chi-square test was used to determine the association of level of wound healing with their selected socio demographic and clinical variables and to compare pre and post wound status. Simple bar diagram, multiple bar diagram, Pie diagram, Doughnut diagram and Box plot were used to represent the data. $P < 0.05$ was considered statistically significant.

3.17 Protection of human rights

The proposed study was conducted after the approval of Ethical committee of Madurai Medical College, Madurai. Informed Consent was obtained from the patients before starting the data collection. Confidentiality was maintained. The formal approval was obtained from the Head of the Department of Surgery. The name of the subjects was not disclosed at any time. Assurance was given that they can withdraw from the study at any time. The possible benefit of participating in the study was explained to the subjects and to the care giver and anonymity was maintained throughout the study.

3.18 Schematic representation of methodology



DATA ANALYSIS AND INTERPRETATION

CHAPTER - IV

DATA ANALYSIS AND INTERPRETATION

Analysis is the process of categorizing, ordering, manipulating and summarizing of data to obtain an answer to the research question. The purpose of the analysis is to reduce the data to intelligible and interpretable form, so that relations for the research problem can be studied and tested.

This chapter deals with analysis and interpretation of data collected from 60 samples that is 30 samples in experimental group I and 30 samples in experimental group II to evaluate the effectiveness of povidone iodine dressing versus normal saline dressing on wound healing among patient with diabetic foot ulcer at Government Rajaji Hospital, Madurai.

The data collected were interpreted under the following sections

The analysis and interpretation of data was organized under the following sections

Section I: Distribution of Socio demographic and clinical variables among patients with diabetic foot ulcer.

Section II: Description of pre test and post test score of wound healing among experimental Group I

Section III: Description of pre test and post test score of wound healing among experimental Group II

Section IV: Comparison of pre test and post test score assessment of wound healing among Experimental group I and experimental group II.

Section V: Association between score of diabetic foot ulcer wound healing with demographic Variables.

Section – I

Distribution of Socio Demographic Variables and Clinical Variables

Table 1

Frequency and percentage distribution of socio demographic variables among patients with diabetic foot ulcer

n = 60

Demographic variables		Group			
		Povidone iodine(n=30)		Normal Saline(n=30)	
		f	%	f	%
Age	30 -40 years	3	10.0%	6	20.0%
	41 -50 years	8	26.7%	9	30.0%
	51 -60 years	10	33.3%	10	33.3%
	> 60 years	9	30.0%	5	16.7%
Gender	Male	22	73.3%	21	70.0%
	Female	8	26.7%	9	30.0%
Religion	Hindu	18	60.0%	12	40.0%
	Christian	5	16.7%	12	40.0%
	Muslim	7	23.3%	6	20.0%
Marital status	Married	28	93.3%	25	83.3%
	Unmarried	2	6.7%	5	16.7%
Mother Tongue	Tamil	27	90.0%	21	70.0%
	Malayalam	1	3.3%	4	13.3%
	Telugu	1	3.3%	2	6.7%
	Others	1	3.4%	3	10.0%
Educational qualification	Non formal education	6	20.0%	5	16.7%
	Primary education	16	53.3%	12	40.0%
	HSC	6	20.0%	11	36.6%
	Graduate	2	6.7%	2	6.7%
Dietary habit	Vegetarian	6	20.0%	4	13.3%
	Non-vegetarian	24	80.0%	26	86.7%

Personal habit	Smoking	7	23.3%	2	6.7%
	Alcoholism	3	10.0%	7	23.2%
	Tobacco	2	6.7%	2	6.7%
	Smoking, Alcoholism	3	10.0%	2	6.7%
	Smoking, alcoholism, tobacco	4	13.3%	9	30.0%
	None	11	36.7%	8	26.7%
Type of occupation	Sedentary worker	11	36.7%	7	23.3%
	Moderate worker	14	46.6%	19	63.4%
	Heavy worker	5	16.7%	4	13.3%
Occupational environment	Highly polluted	6	20.0%	3	10.0%
	Moderate level of pollution	13	43.4%	17	56.6%
	Mild pollution	7	23.3%	8	26.7%
	Pollution free	4	13.3%	2	6.7%
Area of Residence	Urban	8	26.7%	5	16.7%
	Sub urban	9	30.0%	13	43.3%
	Rural	13	43.3%	12	40.0%

The above table reveals the socio demographic variables data of group I and group II patients with diabetic foot ulcer such as Age, Gender, Religion, Marital Status, Mother Tongue, Educational Qualification, Dietary Habit, Personal Habit, Type of Occupation, Occupational Environment and Area of Residence.

Regarding age in experimental group I majority of the patients 10 (33.3%) were 51-60 years, 9 (30.0%) was above 60 years, 8 (26.7%) were between 41-50 years of age, 3 (10.0%) were between 30-40 years of age. In experimental group II majority of the patients 10 (33.3%) belongs to the age group of 51-60 years, 9 (30.0%) were 41-50 years of age, 6 (20.0%) were 30-40 years, 5 (16.7%) were more than 60 years of age.

When dealing with gender in experimental group I majority of the patients 22 (73.3%) were males and 8 (26.7%) were females. In experimental group II majority of the patients 21 (70.0%) were males and 9 (30.0%) were females.

With regards to religion in experimental group I majority of the patients 18 (60.0%) were Hindus, 7 (23.3%) were Muslims and 5 (16.7%) were Christians. In experimental group II 12 (40.0%) were Hindus, 12 (40.0%) were Christian and 6 (20.0%) were Muslims.

When comparing marital status in experimental group I majority of the patients 28 (93.3%) were married and 2 (6.7%) were unmarried. In experimental group II majority of the patients 25 (83.3%) were married and 5 (16.7%) were unmarried.

With regards to mother tongue in experimental group I majority of the patients 27 (90.0%) have Tamil as their mother tongue, 1 (3.3%) have Malayalam as their mother tongue, 1 (3.3%) have Telugu as their mother tongue and 1 (3.4%) have other language as their mother tongue. In experimental group II majority of the patients 21 (70.0%) have Tamil as their mother tongue, 4 (13.3%) have Malayalam as their mother tongue, 2 (6.7%) have Telugu as their mother tongue and 3 (10.0%) have other language as their mother tongue.

When determining the educational qualification in experimental group I majority of the patients 16 (53.3%) had primary education, 6 (20.0%) had no formal education, 6 (20.0%) were HSC and 2 (6.7%) had degree. In experimental group II majority of the patients 12 (40.0%) had primary education, 11 (36.6%) had HSC education, 5 (16.7%) had no formal education and 2 (6.7%) had degree.

Regarding dietary habit in experimental group I majority of the patients 24 (80.0%) were non vegetarian and 6 (20.0%) were vegetarian. In experimental group II

majority of the patients 26 (86.7%) were non vegetarian and 4 (13.3%) were vegetarian.

When comparing the personal habit in experimental group I majority of the patients with diabetic foot ulcer 11 (36.7%) had none of the personal habits, 7 (23.3%) were smoking, 3 (10.0%) had alcoholism, 2 (6.7%) had tobacco, 3 (10.0%) had smoking and alcoholism, 4 (13.3%) had smoking, alcoholism and tobacco. In experimental group II majority of the patients with diabetic foot ulcer 8 (26.7%) had none of the personal habits, 9 (30.0%) had smoking, alcoholism and tobacco, 7 (23.2%) had alcoholism, 2 (6.7%) were smoking, 2 (6.7%) had tobacco, 2 (6.7%) had smoking and alcoholism.

Illustrating the type of occupation in experimental group I majority of the patients with diabetic foot ulcer 14 (46.6%) were moderate worker, 11 (36.7%) were sedentary worker and 5 (16.7%) were heavy worker. In experimental group II majority of the patients with diabetic foot ulcer 19 (63.4%) were moderate worker, 7 (23.3%) were sedentary worker and 4 (13.3%) were heavy worker.

When describing the occupational environment in experimental group I majority of the patients with diabetic foot ulcer 13 (43.4%) had moderate level of pollution, 7 (23.3%) had mild pollution, 6 (20.0%) were highly polluted and 4 (13.3%) were pollution free. In experimental group II majority of the patients with diabetic foot ulcer 17 (56.6%) had moderate level of pollution, 8 (26.7%) had mild pollution, 3 (10.0%) were highly polluted and 2 (6.7%) were pollution free.

While dealing with residence in experimental group I majority of the patients with diabetic foot ulcer 13 (43.3%) belongs to urban, 9 (30.0%) belongs to sub-urban and 8 (26.7%) belongs to rural. In experimental group II majority of the patients with diabetic foot ulcer 13 (43.3%) belongs to sub-urban, 12 (40.0%) belongs to urban and 5 (16.7%) belongs to rural.

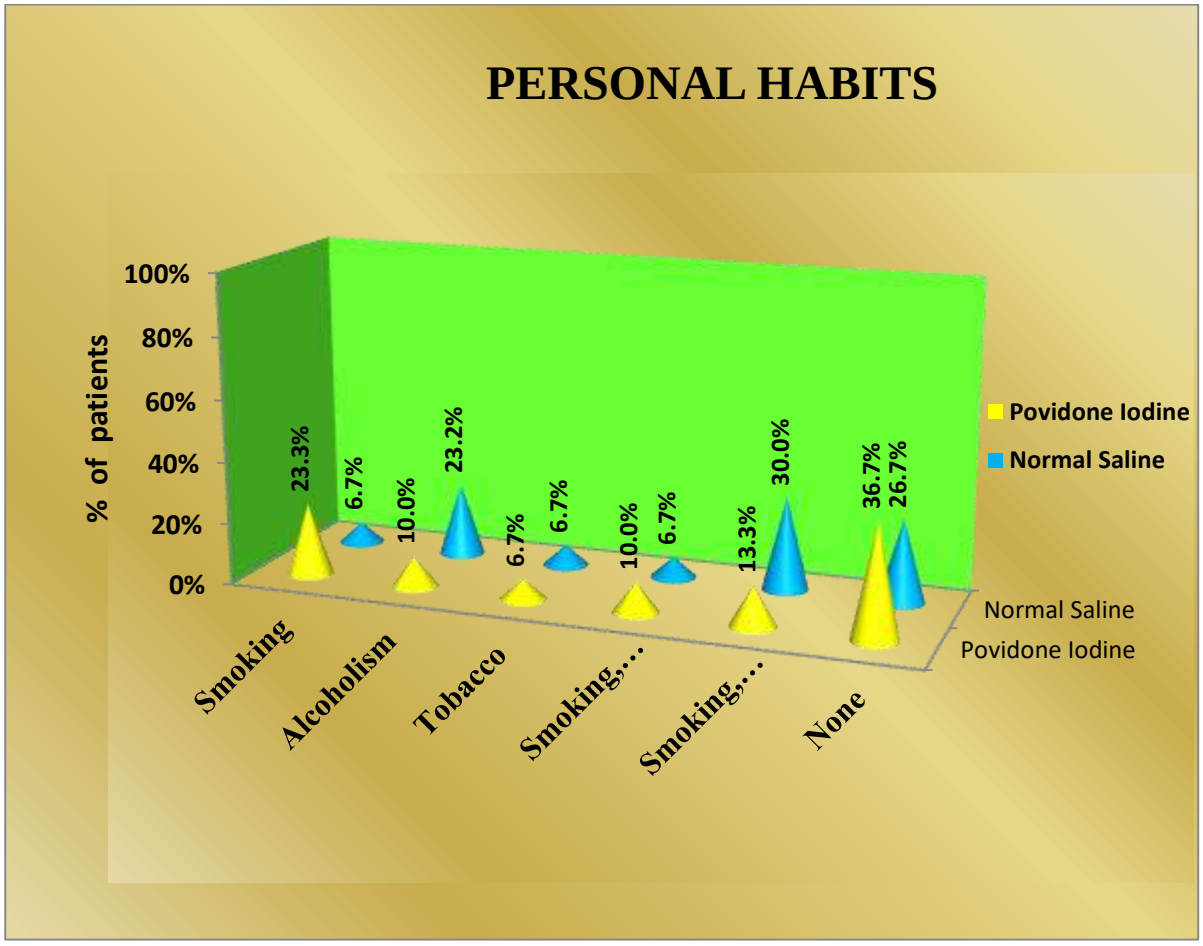


Figure 2: Percentage distribution of personal habits among patients with diabetic foot ulcer.

The above composed multiple cone diagram reveals that in experimental group I majority of the patients with diabetic foot ulcer 11 (36.7%) had none of the personal habits and minor 2 (6.7%) had tobacco usage. In experimental group II majority of the patients with diabetic foot ulcer 9 (30.0%) had smoking, alcoholism and tobacco, and remaining 2 (6.7%) were smoking, 2 (6.7%) had tobacco usage and 2 (6.7%) had smoking and alcoholism.

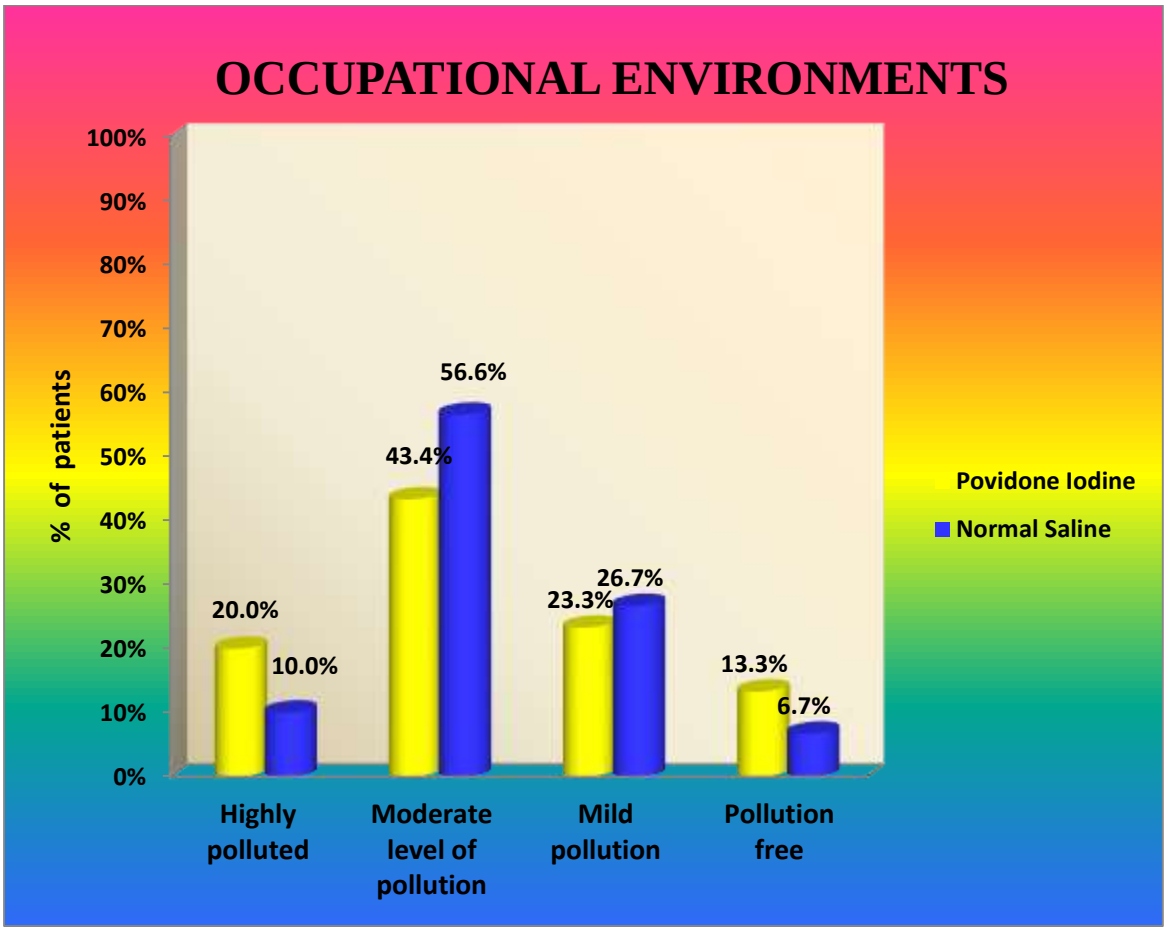


Figure 3: Percentage distribution of occupational environment among patients with diabetic foot ulcer.

The above cylinder diagram portrays that in experimental group I majority of the patients with diabetic foot ulcer 13 (43.4%) had moderate level of pollution and minority 4 (13.3%) were pollution free. In experimental group II majority of the patients with diabetic foot ulcer 17 (56.6%) had moderate level of pollution and minority 2 (6.7%) were pollution free.

Table – 2

Frequency and percentage of clinical variables among patients with diabetic foot ulcer

n=30

Clinical variables		Group			
		Povidone iodine(n=30)		Normal Saline(n=30)	
		f	%	f	%
Type of diabetes	Type 1 Diabetes	3	10.0%	6	20.0%
	Type 2 Diabetes	27	90.0%	24	80.0%
Duration of Diabetes Mellitus	Less than 6 Months	2	6.7%	2	6.7%
	6 Months- 12 months	3	10.0%	4	13.3%
	1 - 5 years	14	46.7%	9	30.0%
	> 5 years	11	36.7%	15	50.0%
Duration of Diabetic Foot Ulcer	Less than 1 month	16	53.3%	9	30.0%
	1 - 6 months	11	36.7%	17	56.7%
	6 - 12 months	3	10.0%	4	13.3%
Site of Diabetic Foot Ulcer	Plantar Surface of the foot	22	73.3%	18	60.0%
	Dorsal surface of the foot	8	26.7%	12	40.0%
Adherence to treatment	Strictly Adherent	8	26.7%	11	36.6%
	Irregular	18	60.0%	17	56.7%
	Not on treatment	4	13.3%	2	6.7%
Type of Anti Diabetic Drug	Oral Hypoglycemic	10	33.3%	16	53.3%
	Insulin	20	66.7%	14	46.7%
Co-Morbid conditions	Hypertension	15	50.0%	11	36.7%
	Coronary Artery Disease	5	16.7%	13	43.3%
	Renal Impairment	4	13.3%	3	10.0%
	None	6	20.0%	3	10.0%
Body Mass Index	Less than 18.5	2	6.7%	2	6.7%
	18.5 - 24.9	6	20.0%	13	43.3%
	25.0 - 29.9	17	56.6%	12	40.0%
	Greater than 30	5	16.7%	3	10.0%
Random Blood Sugar level	Less than 120 mg / dl	3	10.0%	3	10.0%
	121 - 160 mg / dl	3	10.0%	10	33.4%
	161 - 200 mg / dl	14	46.7%	10	33.3%
	Greater than 200 mg / dl	10	33.3%	7	23.3%

With regards to type of diabetes in experimental group I majority of the patients with diabetic foot ulcer 27 (90.0%) were type 2 diabetes and 3 (10.0%) were type I diabetes. In experimental group II majority of the patients with diabetic foot ulcer 24 (80.0%) were type II diabetes and 6 (20.0%) were type I diabetes.

Illustrating the duration of diabetes mellitus in experimental group I majority of the patients with diabetic foot ulcer 14 (46.7%) belongs to 1-5 years, 11 (36.7%) belongs to more than 5 years, 3 (10.0%) belongs to 6 months – 12 months and 2 (6.7%) belongs to less than 1 month. In experimental group II majority of the patients with diabetic foot ulcer 15 (50.0%) belongs to more than 5 years, 9 (30.0%) belongs to 1-5 years, 4 (13.3%) belongs to 6 – 12 months and 2 (6.7%) belongs to less than 1 month.

While comparing the duration of diabetic foot ulcer in experimental group I majority of the patients with diabetic foot ulcer 16 (53.3%) belongs to less than 1 month, 11 (36.7%) belongs to 1 - 6 months and 3 (10.0%) belong to 6 – 12 months. In experimental group II majority of the patients with diabetic foot ulcer 17 (56.7%) belongs to 1 -6 months, 9 (30.0%) belongs to less than 1 month and 4 (13.3%) belongs to 6 – 12 months.

Regarding site of diabetic foot ulcer in experimental group I majority of the patients with diabetic foot ulcer 22 (73.3%) had plantar surface of the foot and 8 (26.7%) had dorsal surface of the foot. In experimental group II majority of the patients with diabetic foot ulcer 18 (60.0%) had plantar surface of the foot and 12 (40.0%) had dorsal surface of the foot.

Illustrating the adherence to treatment in experimental group I majority of the patients with diabetic foot ulcer 18 (60.0%) had irregular treatment adherence, 8 (26.7%) were strictly adherent and 4 (13.3%) were not on treatment. In experimental

group II majority of the patients with diabetic foot ulcer 17 (56.7%) were irregular to treatment, 11 (36.6%) were strictly adherent and 2 (6.7%) were not on treatment.

While dealing with type of anti diabetic drug in experimental group I majority of the patients with diabetic foot ulcer 20 (66.7%) were on insulin and 10 (33.3%) were on oral hypoglycemics. In experimental group II majority of the patients with diabetic foot ulcer 16 (53.3%) were on oral hypoglycemic and 14 (46.7%) were on insulin.

When describing with co - morbid condition in experimental group I majority of the patients with diabetic foot ulcer 15 (50.0%) had hypertension, 5 (16.7%) had coronary artery disease, 4 (13.3%) had renal impairment and 6 (20.0%) had none. In experimental group II majority of the patients with diabetic foot ulcer 13 (43.3%) had coronary artery disease, 11 (36.7%) had hypertension, 3(10.0%) had renal impairment and 3 (10.0%) had none.

Comparing with body mass index in experimental group I majority of the patients with diabetic foot ulcer 17 (56.6%) were between 25.0 -29.9, 6 (20.0%) were between 18.5 -24.9, 5 (16.7%) were greater than 30 and 2 (6.7%) were less than 18.5. In experimental group II majority of the patients with diabetic foot ulcer 13 (43.3%) were between 18.5 -24.9, 12 (40.0%) were between 25.0 -29.9, 3 (10.0%) were greater than 30 and 2 (6.7%) were less than 18.5.

Illustrating with random blood sugar level in experimental group I majority of the patients with diabetic foot ulcer 14 (46.7%) belongs to 161 – 200mg/dl, 10 (33.3%) belongs to greater than 200 mg/dl, 3 (10.0%) belongs to less than 120mg/dl and 3 (10.0%) belongs to 121 – 160 mg/dl. In experimental group II majority of the patients with diabetic foot ulcer 10 (33.3%) belongs to 121 – 160 mg/dl, 10 (33.3%) belongs to 161 – 200mg/dl, 7 (23.3%) belongs to greater than 200 mg/dl and 3 (10.0%) belongs to less than 120mg/dl.

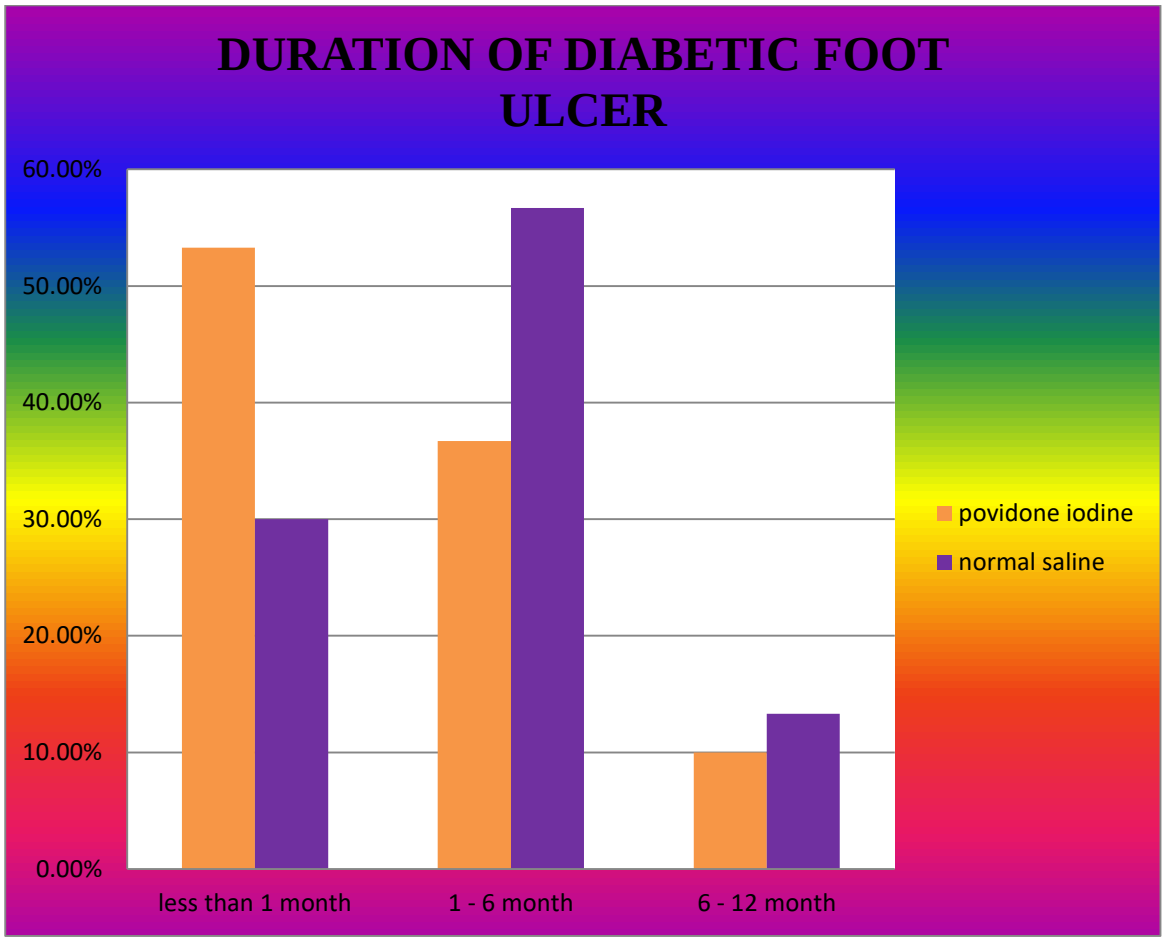


Figure 4: Percentage distribution of duration of diabetic foot ulcer among patients with duration of diabetic foot ulcer.

The above diagram shows that in experimental group I majority of the patients with diabetic foot ulcer 16 (53.3%) belongs to less than 1 month and minority 3 (10.0%) belong to 6 – 12 months of duration. In experimental group II majority of the patients with diabetic foot ulcer 17 (56.7%) belongs to 1 -6 months and minority 4 (13.3%) belongs to 6 – 12 months.

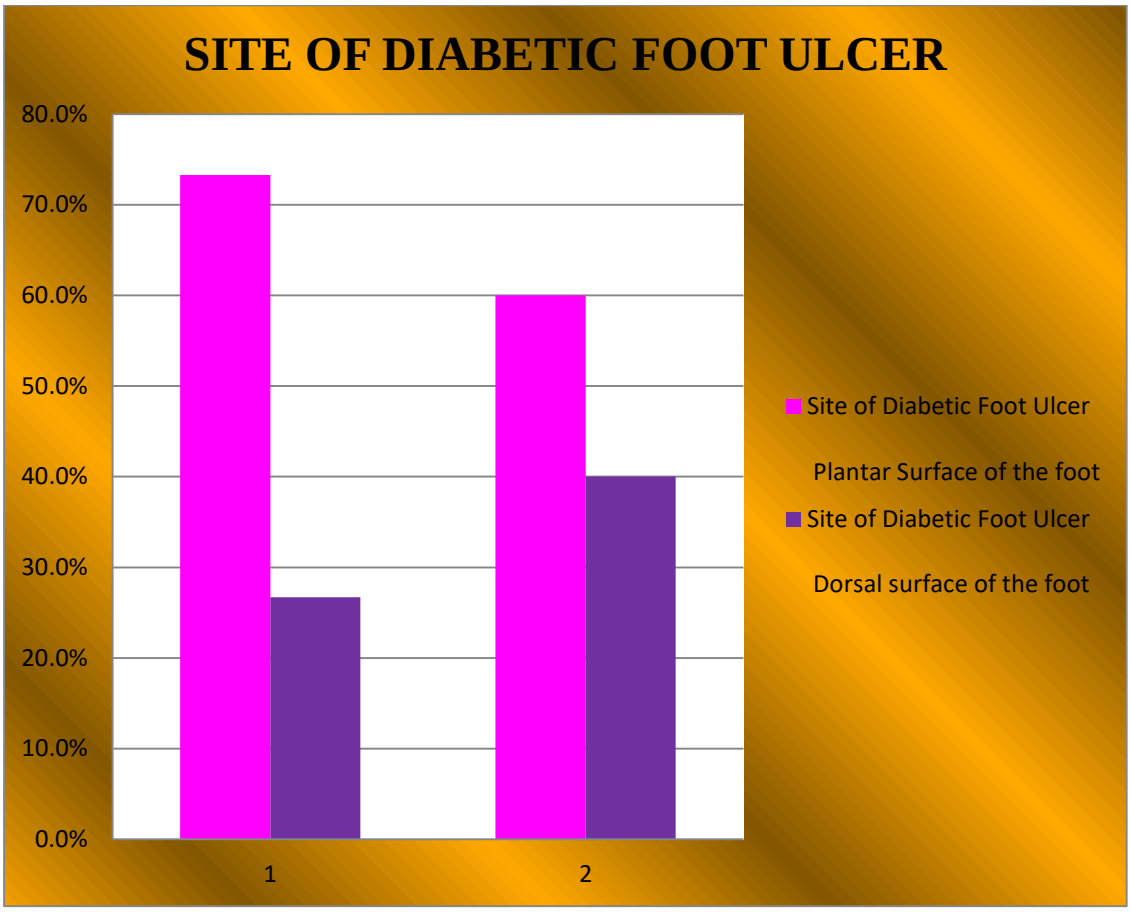


Figure 5: Percentage distribution of site of diabetic foot ulcer among patients with diabetic foot ulcer.

The above diagram states that in experimental group I majority of the patients with diabetic foot ulcer 22 (73.3%) had ulcer in plantar surface of the foot and remaining 8 (26.7%) had ulcer in dorsal surface of the foot. In experimental group II majority of the patients with diabetic foot ulcer 18 (60.0%) had ulcer plantar surface of the foot and remaining 12 (40.0%) had ulcer in dorsal surface of the foot.

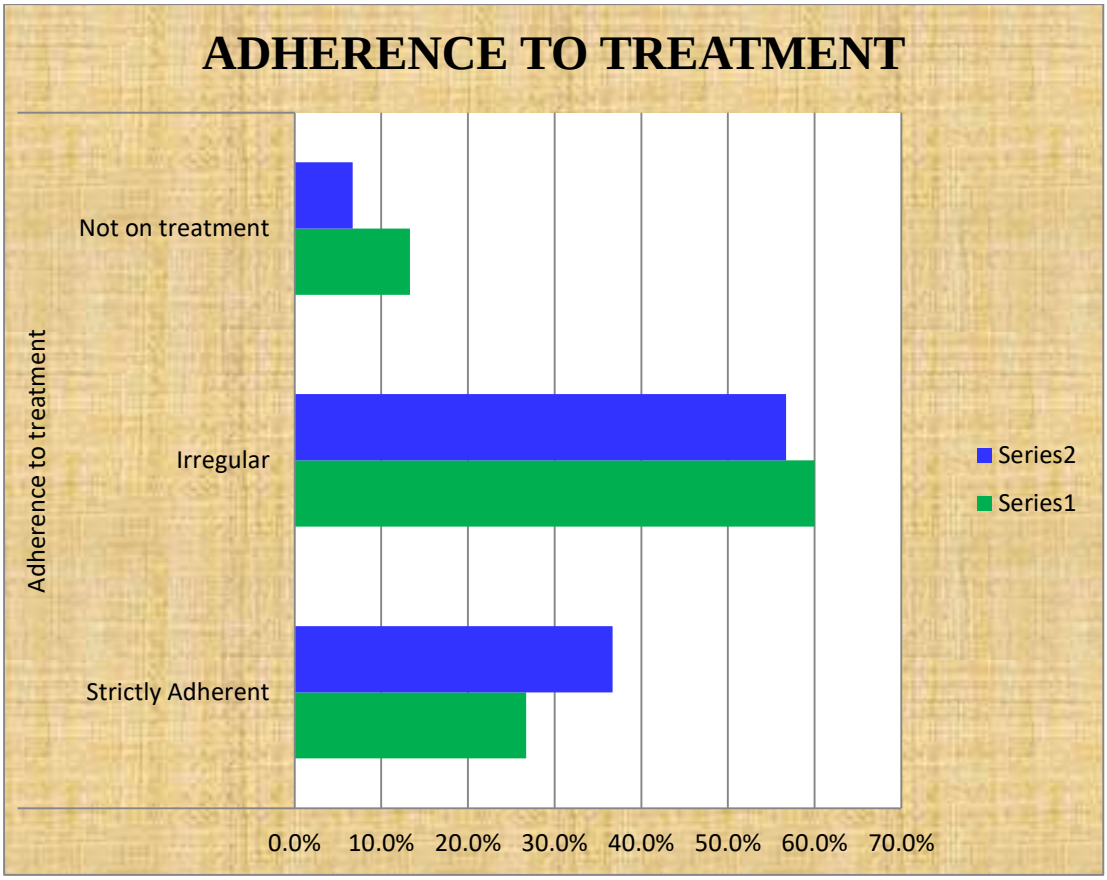


Figure 6: Percentage distribution of adherence to treatment among patients with diabetic foot ulcer.

The above diagram portrays that in experimental group I majority of the patients with diabetic foot ulcer 18 (60.0%) had irregular treatment adherence and minority 4 (13.3%) were not on treatment. In experimental group II majority of the patients with diabetic foot ulcer 17 (56.7%) were irregular to treatment and minority 2 (6.7%) were not on treatment.

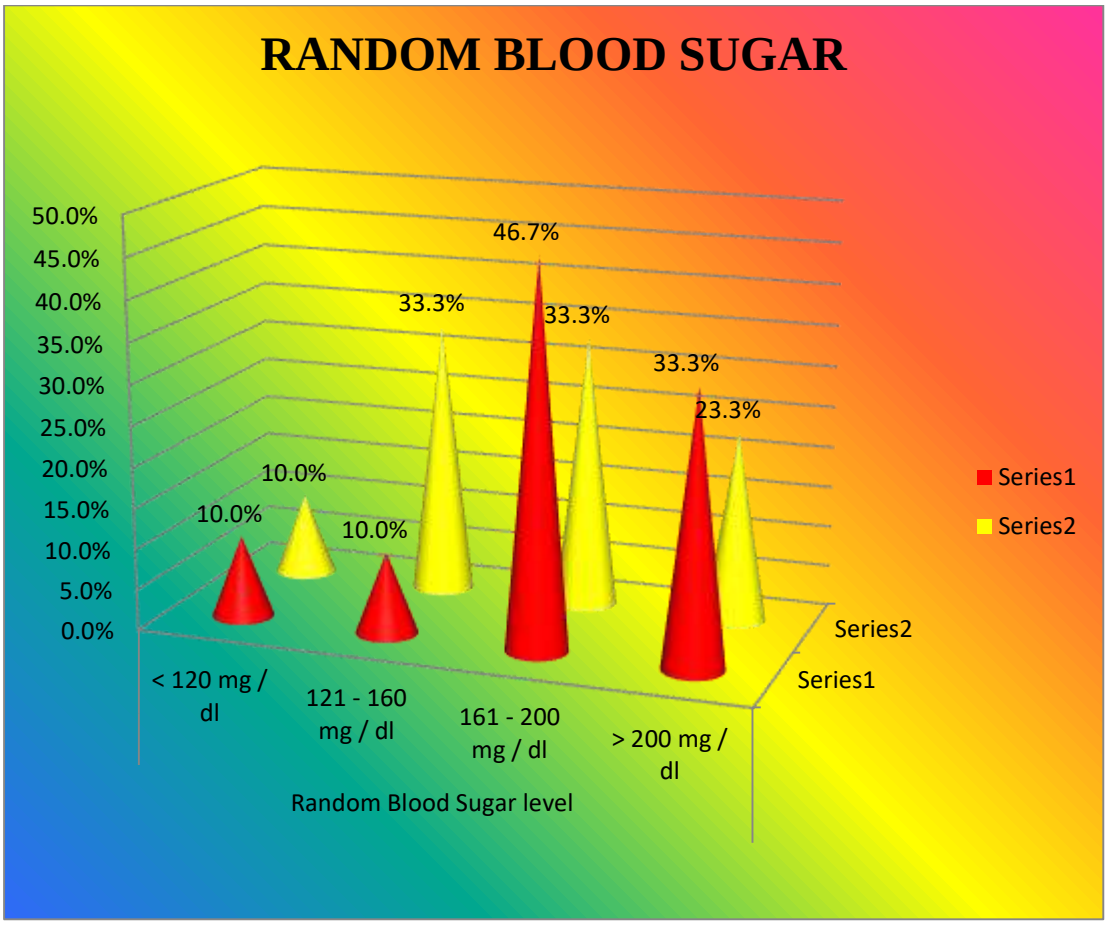


Figure 7: Percentage distribution of random blood sugar level among patients with diabetic foot ulcer.

The above diagram portrays that in experimental group I majority of the patients with diabetic foot ulcer 14 (46.7%) belongs to 161 – 200mg/dl of random blood sugar and minority 3 (10.0%) belongs to 121 – 160 mg/dl of random blood sugar level. In experimental group II majority of the patients with diabetic foot ulcer 10 (33.3%) belongs to 121 – 160 mg/dl, 10 (33.3%) belongs to 161 – 200mg/dl, 7 (23.3%) belongs to greater than 200 mg/dl and 3 (10.0%) belongs to less than 120mg/dl.

Section – II

Description of pre test and post test score of wound healing

Table 3

Frequency and percentage of Pre test and post test level of diabetic foot ulcer wound healing among experimental group I (Povidone iodine dressing group)

n = 30

Level of wound	Test				Mc nemer test		
	Pretest		Posttest		Calculated value	Table value	Significance
	f	%	f	%			
Grade I	0	0.0%	19	63.3%	**$\chi 2=19.00$**	8.34	**P=0.001*** DF=1 Significant**
Grade II	30	100.0%	11	36.7%			
Grade III	0	0.0%	0	0.0%			
Grade IV	0	0.0%	0	0.0%			

* Significant at P≤ 0.05, ** Highly Significant at P ≤ 0.01, *** Very Highly Significant at P ≤0.001

The above table shows that in pre test experimental group I (povidone iodine dressing) all patients are having 100% of Grade II wound score, none of them are having Grade I, Grade III and Grade IV score. In posttest, 63.3% of the patients are having Grade I wound score, 36.7% of the patients are having Grade II wound score and none of them are having Grade III and Grade IV score. Statistical significance was assessed using Extended Mc Nemar's test.

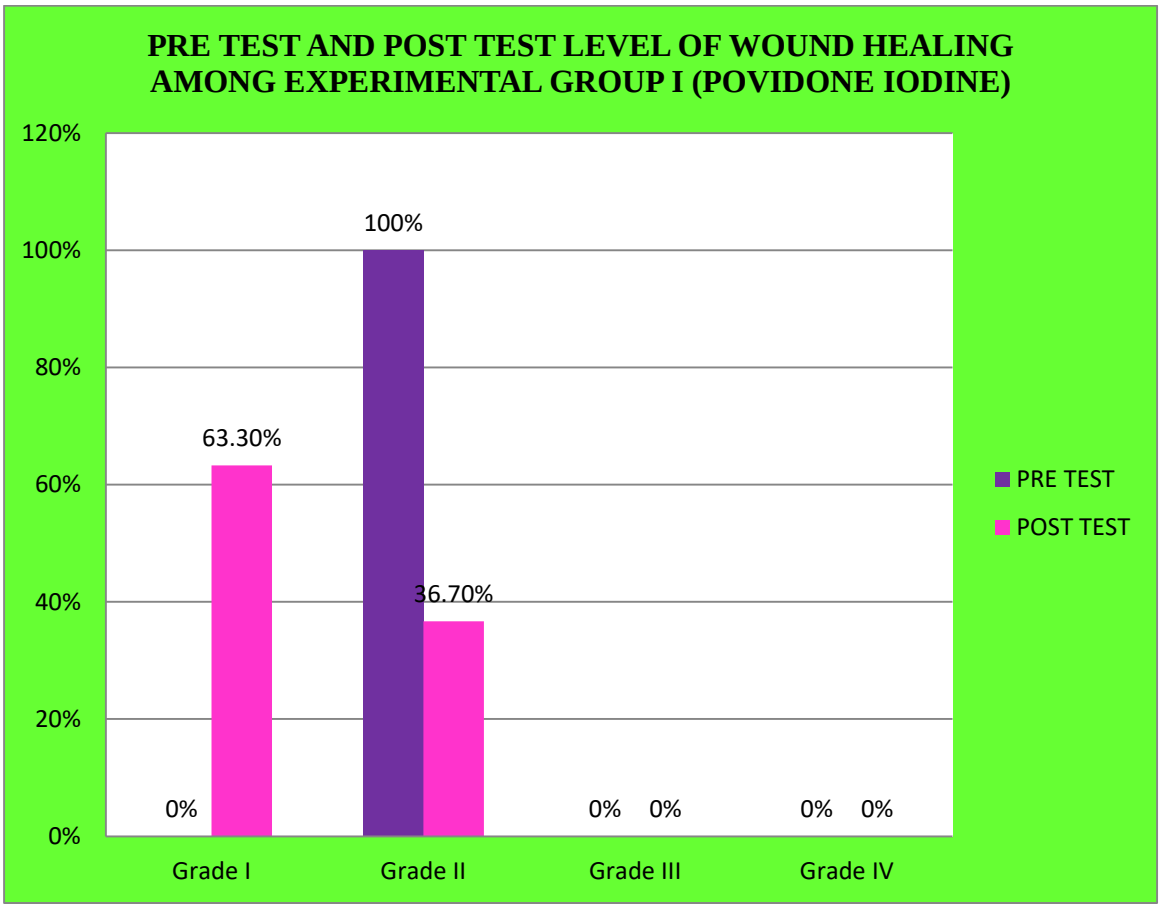


Figure 8: Percentage distribution of pre test and post test level of wound healing among experimental group I (Povidone Iodine dressing).

The above diagram shows that in pre test experimental group I (povidone iodine dressing) all patients are having 100% of Grade II wound score, none of them are having Grade I, Grade III and Grade IV score. In post test, 63.3% of the patients are having Grade I wound score, 36.7% of the patients are having Grade II wound score and none of them are having Grade III and Grade IV score.

Table - 4

Percentage of mean, Standard deviation and Mean difference of pre test and post test Level of wound healing among experimental group I (Povidone iodine dressing)

n = 30

Povidone iodine group	**No. of patients**	**Mean**	**SD**	**Mean Difference**	**% of mean score**	**Student's paired t-test**	**'P' value**
Pretest	30	5.80	0.48	3.27	17.4 %	t=12.45	P=0.001***
Post test	30	2.53	1.38		7.59 %		

* Significant at P≤ 0.05, ** Highly Significant at P ≤ 0.01, *** Very Highly Significant at P ≤0.001

The above table shows that the mean of pretest and post test was 5.80 and 2.53 respectively and standard deviation of pre test and post test was 0.48 and 1.38 respectively. The mean difference was 3.27. The paired t test value was 12.45. This shows that there was a significant difference between pre test and post test scores.

Section - III

Description of pre tes

t and post test score of wound healing

Table - 5

Frequency and percentage distribution of Pre test and post test level of wound healing among experimental group II (Normal Saline Dressing)

n = 30

Level of wound	Test				Extended Mc Nemar's test		
	Pretest		Posttest		Calculated value	Table value	Significance
	f	%	f	%			
Grade I	0	0.0%	10	33.3%	$\chi 2=10.00$	9.0	**P=0.01** DF=1 Significant
Grade II	30	100.0%	20	66.7%			
Grade III	0	0.0%	0	0.0%			
Grade IV	0	0.0%	0	0.0%			

* Significant at P≤ 0.05, ** Highly Significant at P ≤ 0.01, *** Very Highly Significant at P ≤0.001

The above table shows that in pre test experimental group II (Normal Saline dressing) all patients are having 100% of Grade II wound score, none of them are having Grade I, Grade III and Grade IV score. In posttest, 33.3% of the patients are having Grade I wound score, 66.7 % of the patients are having Grade II wound score and none of them are having Grade III and Grade IV score. Statistical significance was assessed using Extended Mc Nemar's test.

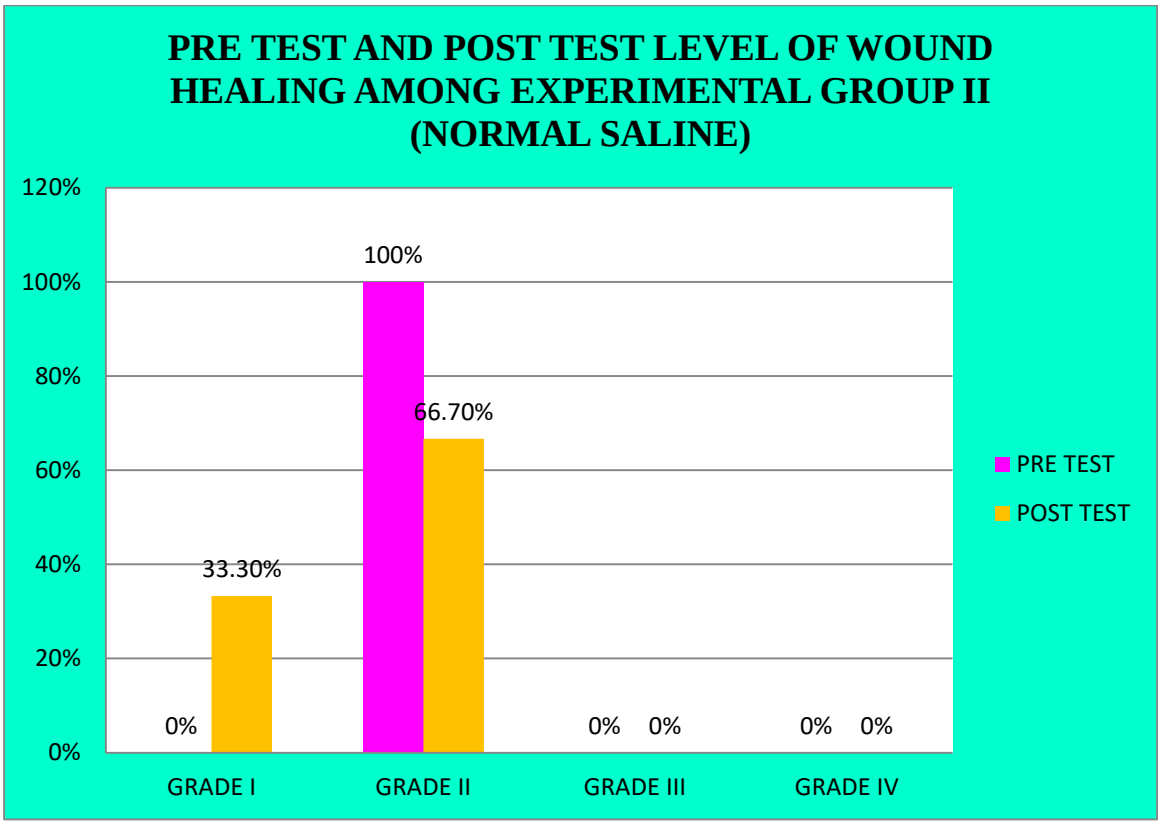


Figure 9: Percentage distribution of pre test and post test level of wound healing among experimental group II (Normal Saline dressing).

The above diagram shows that in pre test experimental group II (Normal Saline dressing) all patients are having 100% of Grade II wound score, none of them are having Grade I, Grade III and Grade IV score. In posttest, 33.3% of the patients are having Grade I wound score, 66.7 % of the patients are having Grade II wound score and none of them are having Grade III and Grade IV score.

Table - 6

Percentage of mean, Standard deviation and Mean difference of pre test and post test level of wound healing among experimental group II (Normal saline dressing)

n = 30

Normal saline group	No. of patients	Mean	SD	Mean Difference	% of mean score	Student's paired t-test	'p' value
Pretest	30	5.97	0.18	1.67	17.91 %	t=6.41	P=0.001***
Posttest	30	4.30	1.42		12.9 %		

* Significant at P≤ 0.05, ** Highly Significant at P ≤ 0.01, *** Very Highly Significant at P ≤0.001

The above table shows that the mean of pretest and post test was 5.97 and 4.30 respectively and standard deviation of pre test and post test was 0.18 and 1.42 respectively. The mean difference was 1.67. The paired t test value was 6.41. This shows that there was a significant difference between pre test and post test scores.

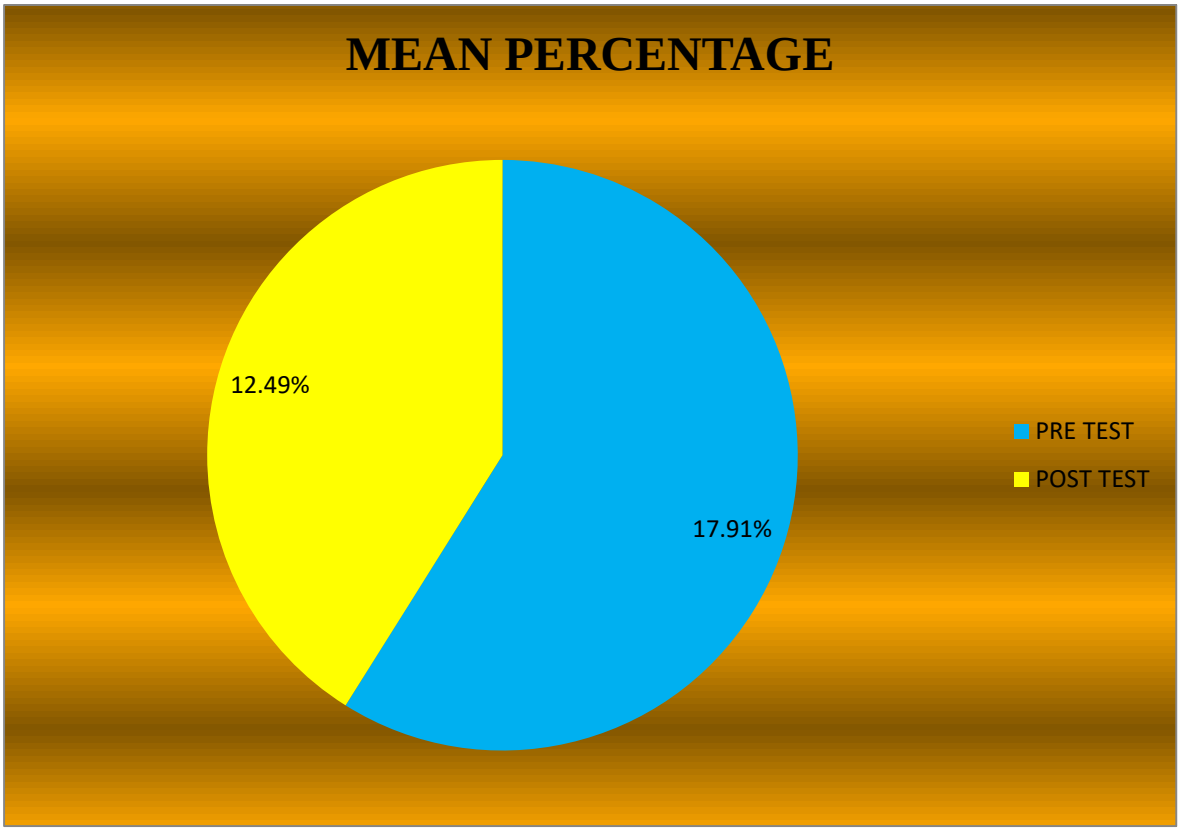


Figure 10: Percentage distribution of effectiveness of Normal saline dressing

The above diagram shows that percentage of mean score of pre test and post test was 17.91 and 12.49 respectively. Hence it is revealed that normal saline dressing is effective in diabetic foot ulcer wound healing.

Section – IV

Comparison of pre test and post test score level of wound healing

Table - 7

Comparison of pre test and post test mean level of wound healing among group I (Povidone Iodine dressing) and group II (Normal Saline dressing)

	Group	No. of patients	Mean	SD	Mean Difference	Student's independent t-test
Pretest	Povidone iodine	30	5.80	0.48	0.17	t=1.76 P=0.09
	Normal saline	30	5.97	0.18		
Posttest	Povidone iodine	30	2.53	1.38	1.77	t=4.88 P=0.001***
	Normal saline	30	4.30	1.42		

* Significant at P≤ 0.05, ** Highly Significant at P ≤ 0.01, *** Very Highly Significant at P ≤0.001

The above table depicts the comparison of mean wound healing score between pre test and post test among experimental group I and experimental group II. A pre test mean of povidone iodine group score was 5.80 with the Standard deviation 0.48. The pre test mean in normal saline group was 5.97 with the standard deviation 0.18. Whereas the post test mean of povidone iodine group was 2.53 with the standard deviation 1.38. The post test mean in normal saline group was 4.30 with the standard deviation 1.42.the mean difference in pre test was 0.17 and post test was 1.77. Student paired 't' test was done to find out the difference between pre test and post test score. Calculated 't' value 4.88 was greater than the table value. Which was significant at 0.001 level.

Table - 8

Proportion difference of percentage of wound reduction score

n = 60

Group		***Max score***	**Mean difference**	**Mean Difference in wound score with 95% Confidence interval**	**Percentage of wound reduction score with 95% Confidence interval**
Povidone iodine	Pretest	15	5.80	3.27(2.73 -3.80)	27.2% (22.8% –31.7%)
	Posttest	15	2.53		
Normal saline	Pretest	15	5.97	1.67(1.14 -2.20)	13.9% (9.5% –18.3%)
	Posttest	15	4.30		

The above table states that on an average, Povidone iodine group patients are having 27.2% reduction score whereas normal saline group patients are having 13.9% of wound reduction score. Povidone iodine group and Normal saline group patients wound score was analysed using mean difference with 95% confidence interval and proportion with 95% Confidence interval

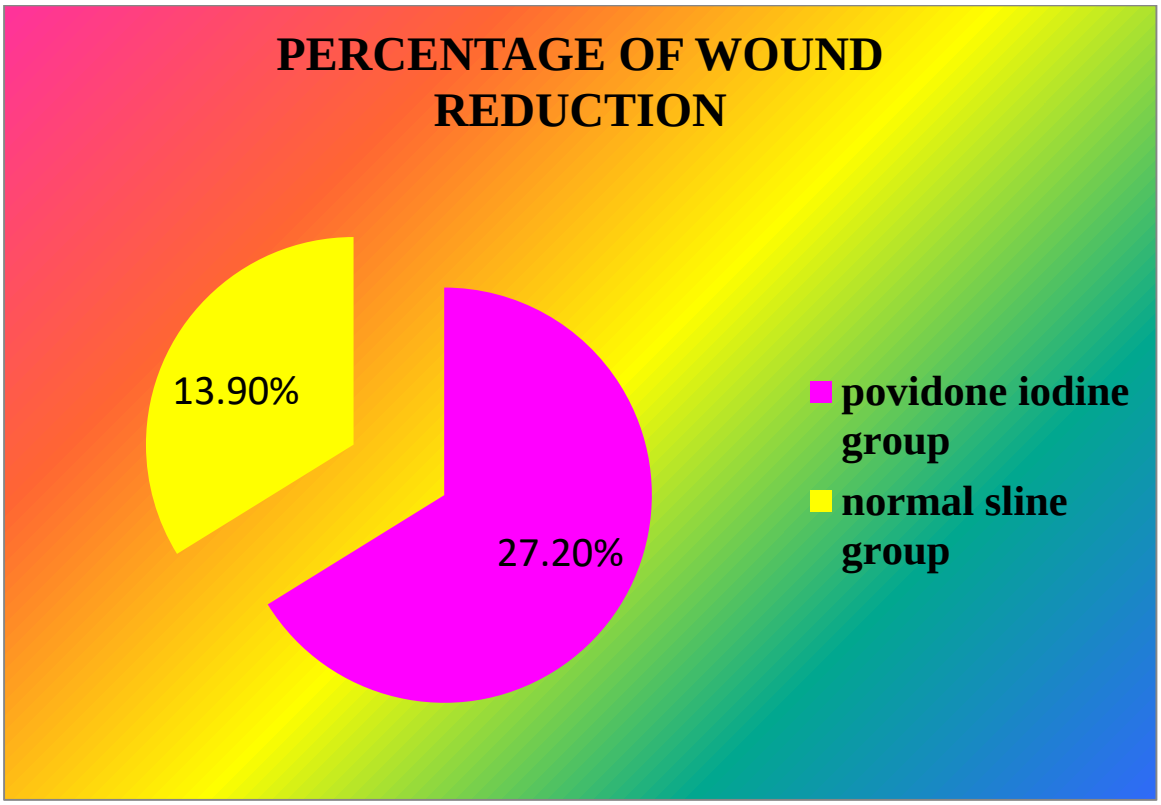


Figure 11: Proportion difference of percentage of wound reduction score

The above diagram states that on an average, Povidone iodine group patients are having 27.2% reduction score whereas normal saline group patients are having 13.9% of wound reduction score. povidone iodine group and Normal saline group patients wound score was analysed using mean difference with 95% confidence interval and proportion with 95% Confidence interval

Section – V

Association between the level of wound healing

Table - 9

Association between the level of wound healing among patients with diabetic foot ulcer with their selected socio demographic variables among group I (Povidone iodine dressing)

n = 30

Demographic variables		Post test level of wound score				Total	Chi square test
		Grade I		Grade II			
		f	%	f	%		
Age	30 -40 years	3	100.0%	0	00.0%	3	**$\chi 2$=10.49 P=0.02* DF=3S**
	41 -50 years	7	87.2%	1	12.5%	8	
	51 -60 years	7	70.0%	3	30.0%	10	
	> 60 years	4	44.5%	5	55.5%	9	
Gender	Male	13	59.1%	9	40.9%	22	$\chi 2$=0.64 P=0.42 DF=1NS
	Female	6	75.0%	2	25.0%	8	
Religion	Hindu	11	61.1%	7	38.9%	18	$\chi 2$=0.75P=0. 68 DF=NS
	Christian	4	80.0%	1	20.0%	5	
	Muslim	4	57.1%	3	42.9%	7	
Marital status	Married	18	64.3%	10	35.7%	28	$\chi 2$=0.16 P=0.68 DF=1 NS
	Unmarried	1	50.0%	1	50.0%	2	
Mother Tongue	Tamil	17	63.0%	10	37.0%	27	$\chi 2$=2.89 P=0.40 DF=3 NS
	Malayalam	1	100.0%	0	0.0%	1	
	Telugu	0	0.0%	1	100.0%	1	
	Others	1	100.0%	0	0.0%	1	
Educational qualification	Non formal education	3	50.0%	3	50.0%	6	$\chi 2$=1.24 P=0.74 DF=3 NS
	Primary education	11	68.8%	5	31.3%	16	
	HSC	4	66.7%	2	33.3%	6	
	Graduate	1	50.0%	1	50.0%	2	

Dietary habit	Vegetarian	5	83.3%	1	16.7%	6	$\chi 2=0.00$ P=1.00 DF=1 NS
	Non-vegetarian	14	58.3%	10	41.7%	24	
Personal habit	Smoking	4	57.1%	3	42.9%	7	$\chi 2=2.10$ P=0.83 DF=5 NS
	Alcoholism	1	33.3%	2	66.7%	3	
	Tobacco	1	50.0%	1	50.0%	2	
	Smoking, Alcoholism	2	66.7%	1	33.3%	3	
	Smoking, alcoholism, tobacco	3	75.0%	1	25.0%	4	
	None	8	72.7%	3	27.3%	11	
Type of occupation	Sedentary worker	8	72.7%	3	27.3%	11	$\chi 2=5.84$P=0.06 DF=2 NS
	Moderate worker	6	42.9%	8	57.1%	14	
	Heavy worker	5	100.0%			5	
Occupational environment	Highly polluted	3	50.0%	3	50.0%	6	$\chi 2=2.99$P=0.33 DF=3 NS
	Moderate level of pollution	10	76.9%	3	23.1%	13	
	Mild pollution	3	42.9%	4	57.1%	7	
	Pollution free	3	75.0%	1	25.0%	4	
Area of Residence	Urban	3	37.5%	5	62.5%	8	**$\chi 2=8.38$P=0.02* DF=2S**
	Sub urban	4	44.5%	5	55.5%	9	
	Rural	12	92.3%	1	7.7%	13	

* Significant at P≤ 0.05, ** Highly Significant at P ≤ 0.01, *** Very Highly Significant at P ≤0.001

The above table explains the association between level of wound healing among patients with diabetic foot ulcer with their socio demographic variables such as age those who are 30 – 40 years ($\chi 2=10.49$ P=0.02*) and area of residence those who are in rural ($\chi 2=8.38$ P=0.02*). All other selected socio demographic variables were not significantly associated with the level of wound healing.

Table - 10

Association between the level of wound healing among patients with diabetic foot ulcer with their selected socio demographic variables among group I (Normal Saline Dressing)

n = 30

Clinical variables		Post test level of wound score				Total	Chi square test
		Grade I		Grade II			
		f	%	f	%		
Type of diabetes	Type 1 Diabetes	3	100.0%	0	0 %	3	$\chi 2$=1.93 P=0.16 DF=1 NS
	Type 2 Diabetes	16	59.3%	11	40.7%	27	
Duration of Diabetes Mellitus	Less than 6 Months	2	100.0%	0	0.0%	2	**$\chi 2$=10.45 P=0.02* DF=3S**
	6 Months- 12 months	3	100.0%	0	0.0%	3	
	1 - 5 years	11	78.6%	3	21.4%	14	
	> 5 years	3	27.2%	8	72.5%	11	
Duration of Diabetic Foot Ulcer	Less than 1 month	12	75.0%	4	25.0%	16	$\chi 2$=2.47 P=0.29 DF=2 NS
	1 - 6 months	5	45.5%	6	54.5%	11	
	6 - 12 months	2	66.7%	1	33.3%	3	
Site of Diabetic Foot Ulcer	Plantar Surface of the foot	15	68.2%	7	31.8%	22	$\chi 2$=0.84 P=0.36 DF=1 NS
	Dorsal surface of the foot	4	50.0%	4	50.0%	8	
Adherence to treatment	Strictly Adherent	8	100.0%	0	0.0%	8	**$\chi 2$=7.63 P=0.02* DF=2S**
	Irregular	10	55.5%	8	44.5%	18	
	Not on treatment	1	25.0%	3	75.0%	4	

Type of Anti Diabetic Drug	Oral Hypoglycaemic	8	80.0%	2	20.0%	10	$\chi 2$=1.79 P=0.18 DF=1 NS
	Insulin	11	55.0%	9	45.0%	20	
CO-Morbid conditions	Hypertension	10	66.7%	5	33.3%	15	$\chi 2$=2.48P=0.46 DF=3 NS
	Coronary Artery Disease	2	40.0%	3	60.0%	5	
	Renal Impairment	2	50.0%	2	50.0%	4	
	None	5	83.3%	1	16.7%	6	
Body Mass Index	Less than 18.5	1	50.0%	1	50.0%	2	$\chi 2$=2.37 P=0.49 DF=3 NS
	18.5 - 24.9	5	83.3%	1	16.7%	6	
	25.0 - 29.9	11	64.7%	6	35.3%	17	
	Greater than 30	2	40.0%	3	60.0%	5	
Random Blood Sugar level	Less than 120 mg /dl	3	100.0%	0	0.0%	3	**$\chi 2$=8.65P=0.03* DF=3S**
	121 - 160 mg / dl	3	100.0%	0	0.0%	3	
	161 - 200 mg / dl	10	71.4%	4	28.6%	14	
	Greater than 200 mg / dl	3	30.0%	7	70.0%	10	

* Significant at P≤ 0.05, ** Highly Significant at P ≤ 0.01, *** Very Highly Significant at P ≤0.001

The above table explains the association between level of wound healing among patients with diabetic foot ulcer with their clinical variables such as Duration of Diabetes Mellitus those who are less than 6 months $\chi 2$=10.45 P=0.02*, Adherence to treatment those who are strictly adherent $\chi 2$=7.63 P=0.02* and random blood sugar those who have less than 120 mg/dl $\chi 2$=8.65P=0.03*. All other selected clinical variables were not significantly associated with the level of wound healing.

Table - 11

Association between diabetic foot ulcer wound healing score and with their socio demographic variables (Normal saline dressing group)

n = 30

Demographic variables		Post test level of wound score				Total	Chi square test
		Grade I		Grade II			
		f	%	f	%		
Age	30 -40 years	5	83.3%	4	16.7%	6	**χ2=12.20 P=0.01** DF=3S**
	41 -50 years	4	44.4%	5	55.6%	9	
	51 -60 years	1	10.0%	9	90.0%	10	
	> 60 years	0	0.0%	5	100.0%	5	
Gender	Male	8	38.1%	13	61.9%	21	χ2=0.71 P=0.39 DF=1 NS
	Female	2	22.2%	7	77.8%	9	
Religion	Hindu	3	25.0%	9	75.0%	12	χ2=0.75P=0.68 DF=2 NS
	Christian	5	41.7%	7	58.3%	12	
	Muslim	2	33.3%	4	66.7%	6	
Marital status	Married	9	36.0%	16	64.0%	25	χ2=0.48 P=0.48 DF=1 NS
	Unmarried	1	20.0%	4	80.0%	5	
Mother Tongue	Tamil	5	23.8%	16	76.2%	21	χ2=6.48 P=0.09 DF=3 NS
	Malayalam	3	75.0%	1	25.0%	4	
	Telugu	0	0.0%	2	100.0%	2	
	Others	2	66.7%	1	33.3%	3	
Educational qualification	Non formal education	0	0.0%	5	100.0%	5	χ2=3.17 P=0.36 DF=3 NS
	Primary education	5	41.7%	7	58.3%	12	
	HSC	4	36.4%	7	63.6%	11	
	Graduate	1	50.0%	1	50.0%	2	
Dietary habit	Vegetarian	0	0.0%	4	100.0%	4	χ2=2.30 P=0.13 DF=1 NS
	Non-vegetarian	10	38.5%	16	61.5%	26	

Personal habit	Smoking	1	50.0%	1	50.0%	2	$\chi 2=4.57$ P=0.47 DF=5 NS
	Alcoholism	2	28.6%	5	71.4%	7	
	Tobacco	0	0.0%	2	100.0%	2	
	Smoking, Alcoholism	0	0.0%	2	100.0%	2	
	Smoking, alcoholism, tobacco	5	55.6%	4	44.4%	9	
	None	2	25.0%	6	75.0%	8	
Type of occupation	Sedentary worker	1	14.3%	6	85.7%	7	$\chi 2=1.74$ P=0.41 DF=2 NS
	Moderate worker	7	36.8%	12	63.2%	19	
	Heavy worker	2	50.0%	2	50.0%	4	
Occupational environment	Highly polluted	3	100.0%	0	0.0%	3	$\chi 2=8.59$ P=0.03 DF=3 NS
	Moderate level of pollution	6	35.3%	11	64.7%	17	
	Mild pollution	1	12.5%	7	87.5%	8	
	Pollution free	0	0.0%	2	100.0%	2	
Area of Residence	Urban	1	20.0%	4	80.0%	5	**$\chi 2=10.25$ P=0.01** DF=2S**
	Sub urban	1	7.7%	12	92.3%	13	
	Rural	8	66.7%	4	33.3%	12	

* Significant at P≤ 0.05, ** Highly Significant at P ≤ 0.01, *** Very Highly Significant at P ≤0.001

The above table explains the association between level of wound healing among patients with diabetic foot ulcer with their socio demographic variables such as age those who are 30 – 40 years $\chi 2=12.20$ P=0.01** and area of residence those who are in rural $\chi 2=10.25$ P=0.01**. All other selected socio demographic variables were not significantly associated with the level of wound healing.

Table - 12

Association between diabetic foot ulcer wound healing score and with their clinical variables (Normal saline dressing group)

n = 30

Clinical variables		Post test level of wound score				Total	Chi square test
		Grade I		Grade II			
		f	%	f	%		
Type of diabetes	Type 1 Diabetes	1	16.7%	5	83.3%	6	$\chi 2$=0.93 P=0.33 DF=1 NS
	Type 2 Diabetes	9	37.5%	15	62.5%	24	
Duration of Diabetes Mellitus	Less than 6 Months	2	100.0%	0	0.0%	2	**$\chi 2$=9.82 P=0.02** DF=1S**
	6 Months- 12 months	3	75.0%	1	25.0%	4	
	1 - 5 years	3	33.3%	6	66.7%	9	
	> 5 years	2	13.3%	13	86.7%	15	
Duration of Diabetic Foot Ulcer	Less than 1 month	4	44.4%	5	55.6%	9	$\chi 2$=1.73P=0.40 DF=1 NS
	1 - 6 months	4	23.5%	13	76.5%	17	
	6 - 12 months	2	50.0%	2	50.0%	4	
Site of Diabetic Foot Ulcer	Plantar Surface of the foot	6	33.3%	12	66.7%	18	$\chi 2$=0.00 P=1.00 DF=1 NS
	dorsal surface of the foot	4	33.3%	8	66.7%	12	
Adherence to treatment	Strictly Adherent	4	36.4%	7	63.6%	11	$\chi 2$=0.41 P=0.81 DF=1 NS
	Irregular	5	29.4%	12	70.6%	17	
	Not on treatment	1	50.0%	1	50.0%	2	
Type of Anti Diabetic Drug	Oral Hypoglycaemic	6	37.5%	10	62.5%	16	$\chi 2$=0.26P=0.60 DF=1 NS
	Insulin	4	28.6%	10	71.4%	14	

CO-Morbid conditions	Hypertension	3	27.3%	8	72.7%	11	$\chi 2$=2.64 P=0.45 DF=1 NS
	Coronary Artery Disease	6	46.2%	7	53.8%	13	
	Renal Impairment	0	0.0%	3	100.0%	3	
	None	1	33.3%	2	66.7%	3	
Body Mass Index	Less than 18.5	0	0.0%	2	100.0%	2	$\chi 2$=3.02P=0.38 DF=1 NS
	18.5 - 24.9	5	38.5%	8	61.5%	13	
	25.0 - 29.9	5	41.7%	7	58.3%	12	
	Greater than 30	0	0.0%	3	100.0%	3	
Random Blood Sugar level	Less than 120 mg / dl	3	100.0%	0	0.0%	3	**$\chi 2$=15.15 P=0.01** DF=1S**
	121 - 160 mg / dl	6	60.0%	4	40.0%	10	
	161 - 200 mg / dl	1	10.0%	9	90.0%	10	
	Greater than 200 mg / dl	0	0.0%	7	100.0%	7	

* Significant at P≤ 0.05, ** Highly Significant at P ≤ 0.01, *** Very Highly Significant at P ≤0.001

The above table explains the association between level of wound healing among patients with diabetic foot ulcer with their clinical variables such as Duration of Diabetes Mellitus those who are less than 6 months $\chi 2$=9.82 P=0.02***, Adherence to treatment those who are strictly adherent $\chi 2$=15.15 P=0.01** and random blood sugar those who have less than 120 mg/dl $\chi 2$=8.65P=0.03*. All other selected clinical variables were not significantly associated with the level of wound healing.

DISCUSSION

CHAPTER – V

DISCUSSION

This chapter deals to find meaningful answer to research questions, the collected data must be processed, analyzed in an order and coherent fashion, so that patterns and relationship can be discussed.

Based on the objectives of the study and hypothesis, this chapter deals with the detailed discussion of the results of the data interpreted from the statistical analysis. The purpose of the study was to evaluate the effectiveness of povidone iodine dressing versus normal saline dressing on wound healing among patients with diabetic foot ulcer at Government Rajaji Hospital, Madurai.

Discussion of Socio Demographic Variables

Regarding age in experimental group I majority of the patients 10 (33.3%) were 51-60 years, 9 (30.0%) was above 60 years, 8 (26.7%) were between 41-50 years of age, 3 (10.0%) were between 30-40 years of age. In experimental group II majority of the patients 10 (33.3%) belongs to the age group of 51-60 years, 9 (30.0%) were 41-50 years of age, 6 (20.0%) were 30-40 years, 5 (16.7%) were more than 60 years of age.

When dealing with gender in experimental group I majority of the patients 22 (73.3%) were males and 8 (26.7%) were females. In experimental group II majority of the patients 21 (70.0%) were males and 9 (30.0%) were females.

With regards to religion in experimental group I majority of the patients 18 (60.0%) were Hindus, 7 (23.3%) were Muslims and 5 (16.7%) were Christians. In

experimental group II 12 (40.0%) were Hindus, 12 (40.0%) were Christian and 6 (20.0%) were Muslims.

When comparing marital status in experimental group I majority of the patients 28 (93.3%) were married and 2 (6.7%) were unmarried. In experimental group II majority of the patients 25 (83.3%) were married and 5 (16.7%) were unmarried.

With regards to mother tongue in experimental group I majority of the patients 27 (90.0%) have Tamil as their mother tongue, 1 (3.3%) have Malayalam as their mother tongue, 1 (3.3%) have Telugu as their mother tongue and 1 (3.4%) have other language as their mother tongue. In experimental group II majority of the patients 21 (70.0%) have Tamil as their mother tongue, 4 (13.3%) have Malayalam as their mother tongue, 2 (6.7%) have Telugu as their mother tongue and 3 (10.0%) have other language as their mother tongue.

When determining the educational qualification in experimental group I majority of the patients 16 (53.3%) had primary education, 6 (20.0%) had no formal education, 6 (20.0%) were HSC and 2 (6.7%) had degree. In experimental group II majority of the patients 12 (40.0%) had primary education, 11 (36.6%) had HSC education, 5 (16.7%) had no formal education and 2 (6.7%) had degree.

Regarding dietary habit in experimental group I majority of the patients 24 (80.0%) were non vegetarian and 6 (20.0%) were vegetarian. In experimental group II majority of the patients 26 (86.7%) were non vegetarian and 4 (13.3%) were vegetarian.

When comparing the personal habit in experimental group I majority of the patients with diabetic foot ulcer 11 (36.7%) had none of the personal habits, 7

(23.3%) were smoking, 3 (10.0%) had alcoholism, 2 (6.7%) had tobacco, 3 (10.0%) had smoking and alcoholism, 4 (13.3%) had smoking, alcoholism and tobacco. In experimental group II majority of the patients with diabetic foot ulcer 8 (26.7%) had none of the personal habits, 9 (30.0%) had smoking, alcoholism and tobacco, 7 (23.2%) had alcoholism, 2 (6.7%) were smoking, 2 (6.7%) had tobacco, 2 (6.7%) had smoking and alcoholism.

Illustrating the type of occupation in experimental group I majority of the patients with diabetic foot ulcer 14 (46.6%) were moderate worker, 11 (36.7%) were sedentary worker and 5 (16.7%) were heavy worker. In experimental group II majority of the patients with diabetic foot ulcer 19 (63.4%) were moderate worker, 7 (23.3%) were sedentary worker and 4 (13.3%) were heavy worker.

When describing the occupational environment in experimental group I majority of the patients with diabetic foot ulcer 13 (43.4%) had moderate level of pollution, 7 (23.3%) had mild pollution, 6 (20.0%) were highly polluted and 4 (13.3%) were pollution free. In experimental group II majority of the patients with diabetic foot ulcer 17 (56.6%) had moderate level of pollution, 8 (26.7%) had mild pollution, 3 (10.0%) were highly polluted and 2 (6.7%) were pollution free.

While dealing with residence in experimental group I majority of the patients with diabetic foot ulcer 13 (43.3%) belongs to urban, 9 (30.0%) belongs to sub-urban and 8 (26.7%) belongs to rural. In experimental group II majority of the patients with diabetic foot ulcer 13 (43.3%) belongs to sub-urban, 12 (40.0%) belongs to urban and 5 (16.7%) belongs to rural.

Discussion of clinical variables

With regards to type of diabetes in experimental group I majority of the patients with diabetic foot ulcer 27 (90.0%) were type 2 diabetes and 3 (10.0%) were type I diabetes. In experimental group II majority of the patients with diabetic foot ulcer 24 (80.0%) were type II diabetes and 6 (20.0%) were type I diabetes.

Illustrating the duration of diabetes mellitus in experimental group I majority of the patients with diabetic foot ulcer 14 (46.7%) belongs to 1-5 years, 11 (36.7%) belongs to more than 5 years, 3 (10.0%) belongs to 6 months – 12 months and 2 (6.7%) belongs to less than 1 month. In experimental group II majority of the patients with diabetic foot ulcer 15 (50.0%) belongs to more than 5 years, 9 (30.0%) belongs to 1-5 years, 4 (13.3%) belongs to 6 – 12 months and 2 (6.7%) belongs to less than 1 month.

While comparing the duration of diabetic foot ulcer in experimental group I majority of the patients with diabetic foot ulcer 16 (53.3%) belongs to less than 1 month, 11 (36.7%) belongs to 1 - 6 months and 3 (10.0%) belong to 6 – 12 months. In experimental group II majority of the patients with diabetic foot ulcer 17 (56.7%) belongs to 1 -6 months, 9 (30.0%) belongs to less than 1 month and 4 (13.3%) belongs to 6 – 12 months.

Regarding site of diabetic foot ulcer in experimental group I majority of the patients with diabetic foot ulcer 22 (73.3%) had plantar surface of the foot and 8 (26.7%) had dorsal surface of the foot. In experimental group II majority of the patients with diabetic foot ulcer 18 (60.0%) had plantar surface of the foot and 12 (40.0%) had dorsal surface of the foot.

Illustrating the adherence to treatment in experimental group I majority of the patients with diabetic foot ulcer 18 (60.0%) had irregular treatment adherence, 8 (26.7%) were strictly adherent and 4 (13.3%) were not on treatment. In experimental group II majority of the patients with diabetic foot ulcer 17 (56.7%) were irregular to treatment, 11 (36.6%) were strictly adherent and 2 (6.7%) were not on treatment.

While dealing with type of anti diabetic drug in experimental group I majority of the patients with diabetic foot ulcer 20 (66.7%) were on insulin and 10 (33.3%) were on oral hypoglycemics. In experimental group II majority of the patients with diabetic foot ulcer 16 (53.3%) were on oral hypoglycemic and 14 (46.7%) were on insulin.

When describing with co - morbid condition in experimental group I majority of the patients with diabetic foot ulcer 15 (50.0%) had hypertension, 5 (16.7%) had coronary artery disease, 4 (13.3%) had renal impairment and 6 (20.0%) had none. In experimental group II majority of the patients with diabetic foot ulcer 13 (43.3%) had coronary artery disease, 11 (36.7%) had hypertension, 3(10.0%) had renal impairment and 3 (10.0%) had none.

Comparing with body mass index in experimental group I majority of the patients with diabetic foot ulcer 17 (56.6%) were between 25.0 -29.9, 6 (20.0%) were between 18.5 -24.9, 5 (16.7%) were greater than 30 and 2 (6.7%) were less than 18.5. In experimental group II majority of the patients with diabetic foot ulcer 13 (43.3%) were between 18.5 -24.9, 12 (40.0%) were between 25.0 -29.9, 3 (10.0%) were greater than 30 and 2 (6.7%) were less than 18.5.

Illustrating with random blood sugar level in experimental group I majority of the patients with diabetic foot ulcer 14 (46.7%) belongs to 161 – 200mg/dl, 10 (33.3%) belongs to greater than 200 mg/dl, 3 (10.0%) belongs to less than 120mg/dl

and 3 (10.0%) belongs to 121 – 160 mg/dl. In experimental group II majority of the patients with diabetic foot ulcer 10 (33.3%) belongs to 121 – 160 mg/dl, 10 (33.3%) belongs to 161 – 200mg/dl, 7 (23.3%) belongs to greater than 200 mg/dl and 3 (10.0%) belongs to less than 120mg/dl.

Findings based on the objectives

The first objective was to assess the level of wound among Group I and Group II patients with diabetic foot ulcer

Among patient with diabetic foot ulcer in experimental group I povidone iodine pretest, all patients are having 100% Grade II wound score, none of them are having Grade I, Grade III and Grade IV score. In experimental group II of normal saline pretest, all patients are having 100% Grade II wound score, none of them are having Grade I, Grade III and Grade IV score.

The present study is consistent with the study conducted by Shailesh K. Shahi M.Sc., Ashok Kumar M.Sc., Ph.D ; Sushil Kumar M.Sc., Ph.D. Surya K Singh MBBS, MD, DM (2013). On descriptive study at Sir Sunderlal Hospital, Institute of Medical Sciences, Varanasi, on Prevalence of Diabetic Foot Ulcer and Associated Risk Factors in Diabetic Patients from North India, 678 diabetic patients were examined of which 97 reported diabetic foot ulcers (DFUs). The study showed that prevalence of diabetic foot ulcer among diabetic patients was 14.30%, 42.16% belonged to urban areas and 70.10% belonged to rural areas. High prevalence of foot ulcers was confirmed among North Indian rural diabetic patients. Age, duration of diabetes, tobacco use, oral hypoglycemic treatment/insulin use and rural location were identified as important risk factors.

The second objective of the study was to evaluate the effectiveness of Povidone iodine Dressing among Group I and Normal Saline Dressing among Group II on wound healing among patients with diabetic foot ulcer.

Among patient with diabetic foot ulcer in experimental group I povidone iodine group pretest, all patients are having 100% Grade II wound score, none of them are having Grade I, Grade III and Grade IV score. In post test, 63.3% of the patients are having Grade I wound score, 36.7% of the patients are having Grade II wound score and none of them are having Grade III and Grade IV score.

In experimental group II of normal saline pretest, all patients are having 100% Grade II wound score, none of them are having Grade I, Grade III and Grade IV score. In post test, 33.3% of the patients are having Grade I wound score, 66.7% of the patients are having Grade II wound score and none of them are having Grade III and Grade IV score.

This study results was also consistent by following studies,

The present study is concurrent with the study conducted by M. J. Smith on Effectiveness of Betadine Dressing on Wound Healing Process at Indira Gandhi Govt. General Hospital and post graduate institute, Pondicherry, quantitative approach by Simple random sampling technique was used to select the samples. 60 samples were selected, The major findings of the study shows that 50% of the patients are at the age group of 36- 50 years, Regarding gender, majority of the samples were males 96.% application of betadine dressing on diabetic wounds is highly effective with controlled glycaemic levels .

Thus the hypothesis H_1: There is a significant difference between the pre test and post test scores among patients with diabetic foot ulcer in Group I, Group II was accepted.

Third objectives was to compare the effectiveness between Povidone iodine dressing (Group I) and Normal saline dressing (Group II) on wound healing among patients with diabetic foot ulcer.

In pretest, Povidone iodine dressing patients are having 5.80 mean score and in post test they are having 2.53 score, in S.D of pre test having 0.48 and post test having 1.38 so the difference is 3.27 wound score. In pretest, Normal saline dressing patients are having 5.97 of mean score and in post test they are having 4.30 score, in S.D of pre test having 0.18 and post test having 1.28, so the difference is 1.67 wound score. The Student's independent t – test value showed statistically significant difference in wound healing (t= 4.88 and p = ≤ 0.05%). The above results shows that there is a statistically improvement in post test level of wound healing between Group I and Group II among patients with diabetic foot ulcer. The study revealed that povidone iodine dressing group have more healing score than normal saline dressing group among patients with diabetic foot ulcer.

The present study is befitting with the study conducted by Shetty, Gautham J (2012) on a prospective, comparative study on conventional dressing (normal saline) versus povidone iodine dressing in non healing lower limb ulcers in A.J.SHETTY institute of medical science. 200 patients with non healing lower limb ulcers were included in the study, they were visually analysed at intervals of 7, 14 and 21 days for epithelialization, infection, exudation and biodegradation and response evaluated by scoring criteria. The results proved that in 88% of the cases there was complete epithelialization (p value 0.05*) in test group compared to control group which was 54%, povidone iodine is an effective dressing in full thickness skin wounds and acts as an efficient to prevent adhesions than the conventional dressing.

Thus the hypothesis H_2: there is a significant difference between the post test level of wound healing among patients with diabetic foot ulcer in Group I (Povidone iodine), Group II (Normal Saline), was accepted.

The fourth objectives was to associate the level of wound among Group I, Group II patients with diabetic foot ulcer with their selected socio demographic variables.

Statistical significance was calculated using chi square test. this study reveals that post test level of wound score and selected socio demographic Variables such as in povidone iodine dressing group Age ($\chi 2=10.49$), Area of Residence ($\chi 2=8.38$), Duration of Diabetes Mellitus ($\chi 2=10.45$), Adherence to treatment ($\chi 2=7.63$) and Random Blood Sugar level ($\chi 2=8.65$). in normal saline dressing group Age ($\chi 2=12.20$), Area of Residence ($\chi 2=10.25$), Duration of Diabetes Mellitus ($\chi 2=9.82$), and Random Blood Sugar level ($\chi 2=15.15$).

The present study is concurrent with the study conducted by Nabil Abd El Fatah Al Kafrawy, Ehab Ahmed Abd El-Atty Mustafa (2014) on descriptive study to assess the risk factors for diabetic foot ulcers (DFUs) in Menoufia University Hospitals, Egypt. 100 patients with diabetic foot ulcer were enrolled using consecutive sampling technique. Study showed that diabetic foot ulcers occurred mostly in patients who had had diabetes for a long duration more than 10 years (94%), smokers (50%), those with diabetic retinopathy (92%), those with previous ulcers (74%), those who had a previous amputation (42%), those with peripheral vascular disease (84%) the study concluded that Peripheral neuropathy, duration of diabetes, peripheral vascular disease, and poor glycemic control were significant predictors of diabetic foot ulcers.

Thus the hypothesis **H_3**: There is a significant association between the level of wound healing with selected socio demographic variables among Group I (Povidone iodine dressing), Group II (Normal Saline dressing) was accepted.

SUMMARY, CONCUSION, IMPLICATION & RECOMMENDATIONS

CHAPTER – VI

SUMMARY, CONCLUSION, IMPLICATION AND RECOMMENDATIONS

This chapter narrates the summary of the study and the conclusion drawn. It also describes the implications for different areas like nursing education, nursing administration, nursing practice and nursing research. It provides the recommendations based on the study.

6.1 Summary

The present study was conducted to evaluate the effectiveness of povidone iodine dressing versus normal saline dressing on wound healing among patients with diabetic foot ulcer at Government Rajaji Hospital, Madurai.

The objective of the study were

1. To assess the level of wound among Group I and Group II patients with diabetic foot ulcer at Government Rajaji Hospital, Madurai.
2. To evaluate the effectiveness of Povidone iodine Dressing among Group I and Normal Saline Dressing among Group II on wound healing among patients with diabetic foot ulcer at Government Rajaji Hospital, Madurai.
3. To compare the effectiveness of Povidone iodine dressing among Group I and Normal saline dressing among Group II on wound healing among patients with diabetic foot ulcer at Government Rajaji Hospital, Madurai.
4. To associate the level of wound among Group I, Group II patients with diabetic foot ulcer with their selected socio demographic variables.

The following hypothesis were tested at 0.05 level

H_1: There is a significant difference between the pre test and post test scores among patients with diabetic foot ulcer in Group I, Group II at Government Rajaji Hospital, Madurai.

H_2: There is a significant difference between the post test level of wound healing among patients with diabetic foot ulcer in Group I, Group II at Government Rajaji Hospital, Madurai.

H_3: There is a significant association between the level of wound healing among Group I, Group II patients with diabetic foot ulcer at Government Rajaji Hospital with their selected socio demographic and clinical variables.

Assumption of the study

- Patients with diabetic foot ulcer have poor wound healing.

The study was conducted at surgical wards at Government Rajaji Hospital, Madurai. The conceptual frame work adopted was Modified Peplau's Interpersonal Relations Theory. Quantitative approach – True experimental, pre test post test research design was adopted. The independent variables are povidone iodine dressing and normal saline dressing and the dependent variable was level of diabetic ulcer wound healing. Non probability consecutive sampling technique was adopted to select 60 samples, 30 samples in group I, patient receiving povidone iodine dressing and 30 samples in group II patients receiving normal saline dressing, picking up the available samples who fulfill the inclusion criteria during the period of data collection. The accessible population for the study was 60 patients with diabetic foot ulcer admitted in surgical wards at Government Rajaji Hospital, Madurai. Intervention carried out

was povidone iodine dressing versus normal saline dressing among patients with diabetic foot ulcer.

The tool used in the study consist of two sections

Section I

- Socio demographic variables
- Clinical variables

Section II

- Modified Perfusion, Extent, Depth, Infection, Sensation (PEDIS) classification and scoring system.

Content validity was obtained from five experts in the field of Medicine and Medical surgical nursing. Pilot study was conducted to find out the feasibility of the study and it did not show any major flaw in the design of the study. On the 1st day, after data collection with Modified Perfusion, Extent, Depth, Infection, Sensation (PEDIS) classification and scoring system, the level of diabetic foot ulcer wound was assessed followed by application of povidone iodine dressing among group I patients with diabetic foot ulcer and application of normal saline dressing among group II patients with diabetic foot ulcer everyday in the morning for 6 consecutive days. Post test was done on 7^{th} day using the same Modified Perfusion, Extent, Depth, Infection, Sensation (PEDIS) classification and scoring system. Data was collected for six weeks from 20.3.2017 to 30.4.2017 and based on the objectives and hypothesis, data were analyzed using descriptive and inferential statistics.

6.2 Major findings of the study

Regarding age in experimental group I majority of the patients 10 (33.3%) were 51-60 years, 9 (30.0%) was above 60 years, 8 (26.7%) were between 41-50 years of age, 3 (10.0%) were between 30-40 years of age. In experimental group II

majority of the patients 10 (33.3%) belongs to the age group of 51-60 years, 9 (30.0%) were 41-50 years of age, 6 (20.0%) were 30-40 years, 5 (16.7%) were more than 60 years of age.

When dealing with gender in experimental group I majority of the patients 22 (73.3%) were males and 8 (26.7%) were females. In experimental group II majority of the patients 21 (70.0%) were males and 9 (30.0%) were females.

With regards to religion in experimental group I majority of the patients 18 (60.0%) were Hindus, 7 (23.3%) were Muslims and 5 (16.7%) were Christians. In experimental group II 12 (40.0%) were Hindus, 12 (40.0%) were Christian and 6 (20.0%) were Muslims.

When comparing marital status in experimental group I majority of the patients 28 (93.3%) were married and 2 (6.7%) were unmarried. In experimental group II majority of the patients 25 (83.3%) were married and 5 (16.7%) were unmarried.

With regards to mother tongue in experimental group I majority of the patients 27 (90.0%) have Tamil as their mother tongue, 1 (3.3%) have Malayalam as their mother tongue, 1 (3.3%) have Telugu as their mother tongue and 1 (3.4%) have other language as their mother tongue. In experimental group II majority of the patients 21 (70.0%) have Tamil as their mother tongue, 4 (13.3%) have Malayalam as their mother tongue, 2 (6.7%) have Telugu as their mother tongue and 3 (10.0%) have other language as their mother tongue.

When determining the educational qualification in experimental group I majority of the patients 16 (53.3%) had primary education, 6 (20.0%) had no formal education, 6 (20.0%) were HSC and 2 (6.7%) had degree. In experimental group II

majority of the patients 12 (40.0%) had primary education, 11 (36.6%) had HSC education, 5 (16.7%) had no formal education and 2 (6.7%) had degree.

Regarding dietary habit in experimental group I majority of the patients 24 (80.0%) were non vegetarian and 6 (20.0%) were vegetarian. In experimental group II majority of the patients 26 (86.7%) were non vegetarian and 4 (13.3%) were vegetarian.

When comparing the personal habit in experimental group I majority of the patients with diabetic foot ulcer 11 (36.7%) had none of the personal habits, 7 (23.3%) were smoking, 3 (10.0%) had alcoholism, 2 (6.7%) had tobacco, 3 (10.0%) had smoking and alcoholism, 4 (13.3%) had smoking, alcoholism and tobacco. In experimental group II majority of the patients with diabetic foot ulcer 8 (26.7%) had none of the personal habits, 9 (30.0%) had smoking, alcoholism and tobacco, 7 (23.2%) had alcoholism, 2 (6.7%) were smoking, 2 (6.7%) had tobacco, 2 (6.7%) had smoking and alcoholism.

Illustrating the type of occupation in experimental group I majority of the patients with diabetic foot ulcer 14 (46.6%) were moderate worker, 11 (36.7%) were sedentary worker and 5 (16.7%) were heavy worker. In experimental group II majority of the patients with diabetic foot ulcer 19 (63.4%) were moderate worker, 7 (23.3%) were sedentary worker and 4 (13.3%) were heavy worker.

When describing the occupational environment in experimental group I majority of the patients with diabetic foot ulcer 13 (43.4%) had moderate level of pollution, 7 (23.3%) had mild pollution, 6 (20.0%) were highly polluted and 4 (13.3%) were pollution free. In experimental group II majority of the patients with

diabetic foot ulcer 17 (56.6%) had moderate level of pollution, 8 (26.7%) had mild pollution, 3 (10.0%) were highly polluted and 2 (6.7%) were pollution free.

While dealing with residence in experimental group I majority of the patients with diabetic foot ulcer 13 (43.3%) belongs to urban, 9 (30.0%) belongs to sub-urban and 8 (26.7%) belongs to rural. In experimental group II majority of the patients with diabetic foot ulcer 13 (43.3%) belongs to sub-urban, 12 (40.0%) belongs to urban and 5 (16.7%) belongs to rural.

With regards to type of diabetes in experimental group I majority of the patients with diabetic foot ulcer 27 (90.0%) were type 2 diabetes and 3 (10.0%) were type I diabetes. In experimental group II majority of the patients with diabetic foot ulcer 24 (80.0%) were type II diabetes and 6 (20.0%) were type I diabetes.

Illustrating the duration of diabetes mellitus in experimental group I majority of the patients with diabetic foot ulcer 14 (46.7%) belongs to 1-5 years, 11 (36.7%) belongs to more than 5 years, 3 (10.0%) belongs to 6 months – 12 months and 2 (6.7%) belongs to less than 1 month. In experimental group II majority of the patients with diabetic foot ulcer 15 (50.0%) belongs to more than 5 years, 9 (30.0%) belongs to 1-5 years, 4 (13.3%) belongs to 6 – 12 months and 2 (6.7%) belongs to less than 1 month.

While comparing the duration of diabetic foot ulcer in experimental group I majority of the patients with diabetic foot ulcer 16 (53.3%) belongs to less than 1 month, 11 (36.7%) belongs to 1 - 6 months and 3 (10.0%) belong to 6 – 12 months. In experimental group II majority of the patients with diabetic foot ulcer 17 (56.7%) belongs to 1 -6 months, 9 (30.0%) belongs to less than 1 month and 4 (13.3%) belongs to 6 – 12 months.

Regarding site of diabetic foot ulcer in experimental group I majority of the patients with diabetic foot ulcer 22 (73.3%) had plantar surface of the foot and 8 (26.7%) had dorsal surface of the foot. In experimental group II majority of the patients with diabetic foot ulcer 18 (60.0%) had plantar surface of the foot and 12 (40.0%) had dorsal surface of the foot.

Illustrating the adherence to treatment in experimental group I majority of the patients with diabetic foot ulcer 18 (60.0%) had irregular treatment adherence, 8 (26.7%) were strictly adherent and 4 (13.3%) were not on treatment. In experimental group II majority of the patients with diabetic foot ulcer 17 (56.7%) were irregular to treatment, 11 (36.6%) were strictly adherent and 2 (6.7%) were not on treatment.

While dealing with type of anti diabetic drug in experimental group I majority of the patients with diabetic foot ulcer 20 (66.7%) were on insulin and 10 (33.3%) were on oral hypoglycemics. In experimental group II majority of the patients with diabetic foot ulcer 16 (53.3%) were on oral hypoglycemic and 14 (46.7%) were on insulin.

When describing with co - morbid condition in experimental group I majority of the patients with diabetic foot ulcer 15 (50.0%) had hypertension, 5 (16.7%) had coronary artery disease, 4 (13.3%) had renal impairment and 6 (20.0%) had none. In experimental group II majority of the patients with diabetic foot ulcer 13 (43.3%) had coronary artery disease, 11 (36.7%) had hypertension, 3(10.0%) had renal impairment and 3 (10.0%) had none.

Comparing with body mass index in experimental group I majority of the patients with diabetic foot ulcer 17 (56.6%) were between 25.0 -29.9, 6 (20.0%) were between 18.5 -24.9, 5 (16.7%) were greater than 30 and 2 (6.7%) were less than 18.5.

In experimental group II majority of the patients with diabetic foot ulcer 13 (43.3%) were between 18.5 -24.9, 12 (40.0%) were between 25.0 -29.9, 3 (10.0%) were greater than 30 and 2 (6.7%) were less than 18.5.

Illustrating with random blood sugar level in experimental group I majority of the patients with diabetic foot ulcer 14 (46.7%) belongs to 161 – 200mg/dl, 10 (33.3%) belongs to greater than 200 mg/dl, 3 (10.0%) belongs to less than 120mg/dl and 3 (10.0%) belongs to 121 – 160 mg/dl. In experimental group II majority of the patients with diabetic foot ulcer 10 (33.3%) belongs to 121 – 160 mg/dl, 10 (33.3%) belongs to 161 – 200mg/dl, 7 (23.3%) belongs to greater than 200 mg/dl and 3 (10.0%) belongs to less than 120mg/dl.

6.3 Conclusion

The statistical evidence proved that the povidone iodine dressing and normal saline dressing was effective in improving the wound healing among group I and group II patients with diabetic foot ulcer. When comparing the level of diabetic foot ulcer wound healing between group I and group II it was proved that povidone iodine dressing was more effective than normal saline dressing. Hence the researcher concluded that povidone iodine dressing is effective than normal saline dressing in diabetic foot ulcer wound healing.

Implication

The investigator had drawn several implications from this study for various areas such as nursing practice, nursing education, nursing administration and nursing research**.**

6.4 Implications for nursing practice

- Nurses working in surgical wards should take responsibility for the assessment diabetic foot ulcers.
- Standardized classification, grading and scoring system for diabetic foot ulcer have to be followed as a part of admission / initial assessment.
- Diabetic foot ulcer dressing incorporating with povidone iodine solution can be followed as it is effective in improving the level of wound healing among diabetic foot ulcer patients in surgical wards.
- Effective wound healing can be achieved only with controlled glycaemic level.

Implications for nursing education

- Educate that appropriate wound dressing help in improving the diabetic foot ulcer wound healing.
- Effective wound dressing is important for the patients with diabetic foot ulcer in surgical wards to maintain and improve the level of wound healing.
- The frequency of wound dressing is an area of controversy and may depend more on the patient's condition and character of the wound

Implications for nursing research

- This study can be a baseline for future studies to build upon and motivate
- A study can be done with large samples and also for long duration.
- A study can be done with other dressing solutions and effectiveness can be analyzed in healing of the diabetic foot ulcer.
- Research is also needed to determine the impact of diabetic foot ulcer on patient's outcome.

Implications for nursing administration

- Administrator should pay special attention to new nurses as well as student nurses to educate and evaluate diabetic foot ulcer in clinical settings.
- Administrator can encourage the nurses to assess the level of diabetic foot ulcer and make it as one of the assessment procedure.
- Administrator should guide the nurses to use standardized classification, grading and scoring system for diabetic foot ulcer
- Articles and materials needed for providing diabetic foot ulcer dressing must be made available by the Administrative department.
- Nursing Administrator can formulate protocols to incorporate the povidone iodine in diabetic foot ulcer dressing.
- In service education programme can be conducted to disseminate the research findings for better practice.

6.5 Recommendations

- A similar study can be replicated with larger sample for better generalization
- A comparative study can be done between povidone iodine dressing and any other wound dressing solutions to evaluate the best.
- A study can be conducted to assess the knowledge, attitude and practice of nursing staff regarding diabetic foot ulcer wound care.
- The effectiveness of povidone iodine dressing in combination with metronidazole wash can also be done
- A similar study can be conducted in other settings like outpatient department and medical wards.

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ANNEXURES

APPENDIX – I

LETTER SEEKING PERMISSION TO CONDUCT STUDY

From

k. Prem Belwin,
II Year M.Sc. Nursing,
College of Nursing,
Madurai Medical College,
Madurai – 20.

To

The Professor & Head of the Department,
Department of General Surgery,
Govt. Rajaji Hospital,
Madurai – 20.

Through Proper Channel,

Respected Sir,

Sub: CON,MMC, Madurai – II year M.Sc. (N) Medical Surgical Nursing Specialty student – permission for conducting a study in Surgical wards in Govt. Rajaji Hospital, MAADURAI – 20, Requesting – Regarding.

This is for your kind information that, I, K. Prem Belwin, II Year M.Sc. Nursing student from College of Nursing, Madurai Medical College, Madurai – 20. In fulfillment of M.Sc. (N) Course, I have a plan to conduct a study on **"A study to evaluate the effectiveness of Povidone iodine dressing versus Normal saline dressing on wound healing among patients with Diabetic foot ulcer at Govt. Rajaji Hospital, Madurai"** at Surgical Wards. I assure you that I will not interfere with the routine activities of the units.

Kindly consider my request and permit me to conduct the study.

Thanking You

Madurai – 20

Yours Faithfully

Prof. D. MARUTHUPANDIAN, M.S., FICS., FAIS.,
Professor of General Surgery
Chief Civil Surgeon
Madurai Medical College
Govt. Rajaji Hospital, Madurai-625 020
Reg. No: 40513

APPENDIX – II

ETHICS COMMITTEE APPROVAL TO CONDUCT THE STUDY

MADURAI MEDICAL COLLEGE
MADURAI, TAMILNADU, INDIA -625 020
(Affiliated to The Tamilnadu Dr.MGR Medical University, Chennai, Tamil Nadu)

Prof Dr V Nagaraajan MD MNAMS DM (Neuro) DSc.,(Neurosciences) DSc (Hons)
Professor Emeritus in Neurosciences, Tamil Nadu Govt Dr MGR Medical University
Chairman, IEC

Dr.M.Shanthi, MD.,
Member Secretary,
Professor of Pharmacology,
Madurai Medical College, Madurai.

Members

1. Dr.K.Meenakshisundaram, MD (Physiology)Vice Principal, Madurai Medical College

2. Dr.Sheela Mallika rani, M.D., Anaesthesia , Medical Superintendent Govt. Rajaji Hosptial, Maudrai

3.Dr.V.T.Premkumar,MD(General Medicine) Professor & HOD of Medicine, Madurai Medical & Govt. Rajaji Hospital, College, Madurai.

4.Dr.D.Maruthupandian, MS., Professor & H.O.D. Surgery, Madurai Medical College & Govt. Rajaji Hosptial, Madurai.

5.Dr.G.Meenakumari, MD., Professor of Pathology, Madurai Medical College, Madurai

6.Mrs.Mercy Immaculate Rubalatha, M.A., B.Ed., Social worker, Gandhi Nagar, Madurai

7.Thiru.Pala.Ramasamy, B.A.,B.L., Advocate, Palam Station Road, Sellur.

8.Thiru.P.K.M.Chelliah, B.A., Businessman,21, Jawahar Street, Gandhi Nagar, Madurai.

ETHICS COMMITTEE CERTIFICATE

Name of the Candidate	:	K.Prem Belwin
Course	:	M.Sc., Nursing (Medical and Surgical Nursing)
Period of Study	:	2015 - 2017
College	:	MADURAI MEDICAL COLLEGE
Research Topic	:	A study to evaluate the effectiveness of povidone Iodine dressing versus normal saline dressing on wound healing among patients with diabetic foot ulcer at Govt. Rajaji Hospital, Madurai.
Ethical Committee as on	:	08.02.2017

The Ethics Committee, Madurai Medical College has decided to inform that your Research proposal is accepted.

Member Secretary — Prof Dr.V.Nagaraajan M.D., MNAMS, D.M., Dsc.,(Neuro), Dsc (Hons) CHAIRMAN IEC - Madurai Medical College Madurai — Dean / Convenor — DEAN Madurai Medical College Madurai-20

APPENDIX – III

CONTENT VALIDITY CERTIFICATES

This is to certify that the tool

SECTION A - Demographic Data

SECTION B – Modified - Perfusion Extent Depth Infection Sensation - (PEDIS) Scoring system.

Prepared for data collection by, **Mr. K. PREM BELWIN**, II year M.Sc.(N) student, College of Nursing, Madurai Medical College, Madurai, Who has undertaken the study field on thesis entitled **"A study to evaluate the effectiveness of Povidone iodine dressing versus Normal saline dressing on wound healing among patients with Diabetic foot ulcer at Government Rajaji Hospital Madurai."** has been validated by me.

13/4/17

SIGNATURE OF THE EXPERT

NAME:

Prof. D. MARUTHUPANDIAN,
M.S.,FICS.,FAIS.,
Professor of General Surgery
Chief Civil Surgeon
Madurai Medical College
Govt. Rajaji Hospital, Madurai-625 020
Reg. No: 40513

DESIGNATION:

ADDRESS:

DATE:

CONTENT VALIDITY CERTIFICATE

This is to certify that the tool

SECTION A - Demographic Data

SECTION B – PEDIS -

Prepared for data collection by, Mr.K. PREM BELWIN, II year M.Sc (N) student, College of Nursing, Madurai Medical College, Madurai, Who has undertaken the study field on thesis entitled "A study to evaluate the effectiveness of Povidone iodine dressing versus Normal saline dressing on wound healing among patients with Diabetic foot ulcer at Government Rajaji Hospital Madurai." has been validated by me.

V. Vathana

SIGNATURE OF THE EXPERT

NAME: V. VATHANA

DESIGNATION: PROFESSOR

ADDRESS: MADHA COLLEGE OF NURSING CHENNAI-69

DATE: 11/03/2017

MADHA COLLEGE OF NURSING 11 MAR 2017 CHENNAI - 600 069

CONTENT VALIDITY CERTIFICATE

This is to certify that the tool

SECTION: A - Demographic Data

SECTION: B – PEDIS – Perfusion Extent Depth Infection Sensation Grading scale.

Prepared for data collection by, Mr. K. PREM BELWIN, II year M.Sc (N) student, College of Nursing, Madurai Medical College, Madurai, Who has undertaken the study field on thesis entitled **"**A study to evaluate the effectiveness of Povidone iodine dressing versus Normal saline dressing on wound healing among patients with Diabetic foot ulcer at Government Rajaji Hospital Madurai.**"** has been validated by me.

SIGNATURE OF THE EXPERT

NAME: SARJUT BHARATHI. N

DESIGNATION: ASSOC. PROFESSOR

ADDRESS: SACRED HEART NURSING COLLEGE

DATE: 6/3/17.

SACRED HEART NURSING COLLEGE

4/285, COLLEGE ROAD

CONTENT VALIDITY CERTIFICATE

This is to certify that the tool

SECTION A - Demographic Data

SECTION B – PEDIS -

Prepared for data collection by, Mr. K. PREM BELWIN, II year M.Sc (N) student, College of Nursing, Madurai Medical College, Madurai, Who has undertaken the study field on thesis entitled "A study to evaluate the effectiveness of Povidone iodine dressing versus Normal saline dressing on wound healing among patients with Diabetic foot ulcer at Government Rajaji Hospital Madurai." has been validated by me.

SIGNATURE OF THE EXPERT

NAME: Dr. S. Chandrakala.

DESIGNATION: Principal

ADDRESS:

Principal
Velammal College of Nursing
Madurai-625 009

DATE:

CONTENT VALIDITY CERTIFICATE

This is to certify that the tool

SECTION: A - Demographic Data

SECTION: B – PEDIS – Perfusion Extent Depth Infection Sensation Grading scale.

Prepared for data collection by, Mr. K. PREM BELWIN, II year M.Sc (N) student, College of Nursing, Madurai Medical College, Madurai, Who has undertaken the study field on thesis entitled **"A study to evaluate the effectiveness of Povidone iodine dressing versus Normal saline dressing on wound healing among patients with Diabetic foot ulcer at Government Rajaji Hospital Madurai."** has been validated by me.

SIGNATURE OF THE EXPERT

NAME: ANDAL P

DESIGNATION: Professor

ADDRESS: Sacred Heart Nursing College Madurai-20

DATE: 4.3.17

SACRED HEART NURSING COLLEGE
4/226, COLLEGE ROAD

APPENDIX – IV

INFORMED CONSENT FORM

Name:

Date:

I have been well explained about the povidone iodine dressing on diabetic foot ulcer wound healing. The uses and its complications is clearly explained to the patients. Here by agree to participate in this study if any complications arises the doctors, nurses and the management is not responsible for that. I have given full freedom to leave the study at any time and I am assured by the researcher that my information will be confidential

Signature

INFORMED CONSENT FORM

Name:

Date:

I have been well explained about the normal saline dressing on diabetic foot ulcer wound healing. The uses and its complications is clearly explained to the patients. Here by agree to participate in this study if any complications arises the doctors, nurses and the management is not responsible for that. I have given full freedom to leave the study at any time and I am assured by the researcher that my information will be confidential

Signature

ஒப்புதல் அறிக்கை

பெயர்: தேதி:

எனக்கு இந்த ஆய்வைப் பற்றிய முழு விவரம் விளக்கமாக எடுத்துரைக்கப்பட்டது. இந்த ஆய்வில் பங்கு பெறுவதில் உள்ள நன்மைகள் மற்றும் தீமைகள் பற்றி நான் புரிந்து கொண்டேன். நான் இந்த ஆய்வில் தானாகவே முன் வந்து என பங்குபெற சம்மதிக்கிறேன். மேலும் இந்த ஆய்வில் இருந்து எந்த நேரமும் விலகிக் கொள்ள முழு அனுமதி வழங்கப்பட்டுள்ளது. என்னுடைய சிகிச்சை ஆவணங்களைப் பார்வையிட்டு அதில் உள்ள விவரங்களை ஆய்வில் பயன்படுத்திக் கொள்ள அனுமதி அளிக்கின்றேன். என்னுடைய பெயர் மற்றும் அடையாளங்கள் ரகசியமாக வைத்துக் கொள்ளப்படும் என்றும் எனக்கு உறுதியளிக்கப்பட்டுள்ளது.

கையொப்பம்

APPENDIX – V

RESEARCH TOOL – ENGLISH

SOCIO DEMOGRAPHIC DATA

SECTION-A

NAME: DATE:

WARD: SAMPLE NO:

1. **Age** **[ ]**
    a) 30 - 40 yrs
    b) 41- 50 yrs
    c) 51- 60 yrs
    d) More than 60 yrs
2. **Gender** **[ ]**
    a) Male
    b) Female
3. **Religion** **[ ]**
    a) Hindu
    b) Christian
    c) Muslim
    d) Others
4. **Marital status** **[ ]**
    a) Married
    b) Un married
5. **Mother Tongue** **[ ]**
    a) Tamil
    b) Malayalam
    c) Telugu
    d) Others

6. **Educational qualification** [ ]

a) Non formal education

b) Primary education

c) HSC

d) Graduate

7. **Dietary habit** [ ]

a) Vegetarian

b) Non-vegetarian

8. Personal Habits **[ ]**

a) Smoking

b) Alcoholism

c) Tobacco

d) Smoking and alcoholism

e) Smoking, alcoholism and tobacco

f) None

9. Type of occupation **[ ]**

a) Sedentary worker

b) Moderate worker

c) Heavy worker

10. Occupational Environment **[ ]**

a) Highly polluted

b) Moderate level of pollution

c) Mild pollution

d) Pollution free

11. Area of residence **[ ]**

a) Urban

b) Sub urban

c) Rural

CLINICAL VARIABLES

1. Type of Diabetes [ ]

a) Type 1 Diabetes

b) Type 2 Diabetes

2. Duration of Diabetes Mellitus **[ ]**

a) Less than 6 Months

b) More than 6 Months

c) More than 1 Year

d) More than 5 Years

3. Duration of diabetic foot ulcer **[ ]**

a) Less than 1 month

b) Less than 6 months

c) More than 6 months

d) More than 1 year

4. Site of diabetic foot ulcer **[ ]**

a) Plantar Surface of the foot

b) Dorsal surface of the foot

5. Adherence to treatment **[ ]**

a) Strictly Adherent

b) Irregular

c) Not on treatment

6. Type of Anti Diabetic Drug **[ ]**

a. Oral Hypoglycaemic

b. Insulin

7. Co-morbid conditions **[ ]**

a) Hypertension
b) Coronary Artery Disease
c) Renal Impairment
d) None

8. Body Mass Index **[ ]**

a) Less than 18.5
b) 18.5 – 24.9
c) 25 – 29.9
d) Greater than 30

9. Random Blood Sugar Level **[ ]**

a) Less than 120 mg / dl
b) 121 – 160 mg / dl
c) 161 – 200 mg / dl
d) Greater than 200 mg / dl

MODIFIED PEDIS CLASSIFICATION AND SCORING SYSTEM

S.NO	PEDIS	SCORES
1.	**PERFUSION** 0- No Peripheral Arterial Disease 1- Peripheral Arterial Disease , No Critical Limb Ischemia 2- CLI	
2.	**EXTENT** 0- Skin intact 1- <1cm^2 2- 1-3 cm^2 3- > 3 cm^2	
3.	**DEPTH** 0- Skin intact 1- Superficial 2- Fascia, muscle tendon 3- Bone or joint	
4.	**INFECTION** 0- None 1- Surface 2- Abscess, fasciitis, septic arthritis 3- SIRS	
5.	**SENSATION** 0- No loss 1- Loss	

Scoring interpretation:

1-3 = GRADE I

4-6 = GRADE II

7-9 = GRADE III

10-12= GRADE IV

APPENDIX – VI

RESEARCH TOOL - TAMIL

தன்னிலை விபரக்குறிப்பு

1. வயது [ ]

அ. 30-40

ஆ. 41-50

இ. 51-60

ஈ. 60 வயதுக்கு மேல்

2. பாலினம் [ ]

அ. ஆண்

ஆ. பெண்

3. மதம் [ ]

அ. இந்து

ஆ. கிறிஸ்துவர்

இ. இஸ்லாமியர்

ஈ. பிறமதங்கள்

4. திருமணநிலை [ ]

அ. திருமணமானவர்

ஆ. திருமணமாகாதவர்

5. தாய்மொழி [ ]

அ. தமிழ்

ஆ. மலையாளம்

இ. தெலுங்கு

ஈ. பிறமொழி

6. கல்வித்தகுதி [ ]

அ. படிக்கவில்லை

ஆ. ஆரம்பக்கல்வி

இ. மேல் நிலை

ஈ. பட்டப்படிப்பு

7. உணவு பழக்கம் [ ]

அ. சைவம்

ஆ. அசைவம்

8. தனிப்பட்டப் பழக்கவழக்கங்கள் [ ]

அ. புகைப்பிடித்தல்

ஆ. மதுஅருந்துதல்

இ. புகையிலை பயன்படுத்துதல்

ஈ. புகைப்பிடித்தல் மற்றும் மதுஅருந்துதல்

உ. புகைப்பிடித்தல், மதுஅருந்துதல் மற்றும் புகையிலை பயன்படுத்துதல்

ஊ. ஒன்றும் இல்லை.

9. தொழில் நிலை [ ]

அ. உடல் உழைப்பு இல்லாதத் தொழில்

ஆ. மிதமானத்தொழில்

இ. கனரகத்தொழில்

10. இருப்பிடத்தின் சுற்றுச்சூழல் [ ]

அ. மிகவும் மாசுபட்ட சூழல்

ஆ. மிதமான மாசுபட்ட சூழல்

இ. குறைவான மாசுபட்ட சூழல்

ஈ. மாசற்ற சூழல்

11. குடியிருப்பு பகுதி [ ]

அ. நகரம்

ஆ. புறநகர்

இ. கிராமம்

மருத்துவ விவரக்குறிப்பு

1. நீரிழிவு நோயின் வகை [ ]

அ. முதலாவதுவகை நீரிழிவு

ஆ. இரண்டாவதுவகை நீரிழிவு

2. நீரிழிவு நோயின் நீடிப்புக்காலம் [ ]

அ. ஆறுமாதத்திற்குள்

ஆ. ஆறுமாதத்திற்க மேல்

இ. ஒருவருடத்திற்கு மேல்

ஈ. ஐந்து வருடத்திற்கு மேல்

3. நீரிழிவுநோய் கால்புண்ணின் நீடிப்புக்காலம் [ ]

அ. ஒருமாதத்திற்குள்

ஆ. ஒருமாதத்திற்கு மேல்

இ. ஆறுமாதத்திற்கு மேல்

ஈ. ஒருவருடத்திற்கு மேல்

4. நீரிழிவு நோய் கால்புண்ணின் இடம் [ ]

அ. கால் கடைநா

ஆ. கால் முன்புறம்

5. சிகிச்சையை பின்பற்றுதல் [ ]

அ. தவறாமல் பின்பற்றுதல்

ஆ. ஒழுங்கற்றுப்பின் பற்றுதல்

இ. சிகிச்சையின்மை

6. எதிர்ப்பு நீரிழிவு மருந்து [ ]

அ. வாய்வழி மருந்து

ஆ. இன்சுலின்

7. உடன் நோய்கள் [ ]

அ. உயர் இரத்த அழுத்தம்

ஆ. கரோனரி இதய நோய்

இ. சிறுநீரக நோய்

ஈ. எதுவும் இல்லை

8. உடல்நிறை குறியீடு [ ]

அ. 18.5 க்கு கீழ்

ஆ. 18.5-24.9

இ. 25-29.9

ஈ. 30க்கு மேல்

9. சீரற்ற இரத்த சர்க்கரை அளவு [ ]

அ. 120 க்கு கீழ்

ஆ. 121 - 160

இ. 161 - 200

ஈ. 200 க்கு மேல்

APPENDIX – VII

CERTIFICATE FOR ENGLISH EDITING

TO WHOM SO EVER IT MAY CONCERN

This is to certify that the dissertation by **Mr.K. PREM BELWIN**, II Year M.Sc Nursing student, College of Nursing, Madurai Medical College, Madurai, who has undertaken the study field on dissertation entitled **"A study to evaluate the effectiveness of Povidone iodine dressing versus Normal saline dressing on wound healing among patients with Diabetic foot ulcer at Government Rajaji Hospital Madurai".** Has been edited for English language appropriateness.

SIGNATURE

NAME: S. BAGRUDEEN,

DESIGNATION: S. BAGRUDEEN, MA.,BSc.,M.Ed.,
P/T. Professor of English
(I-Year BSc Nursing)

INSTITUTION: Madurai Medical College
Madurai - 625020.

APPENDIX – VIII

CERTIFICATE FOR TAMIL EDITING

TO WHOM SO EVER IT MAY CONCERN

This is to certify that the dissertation by **Mr. K. PREM BELWIN,** II Year M.Sc Nursing student, College of Nursing, Madurai Medical College, Madurai, who has undertaken the study field on dissertation entitled **"A study to evaluate the effectiveness of Povidone iodine dressing versus Normal saline dressing on wound healing among patients with Diabetic foot ulcer at Government Rajaji Hospital Madurai".** Has been edited for Tamil language appropriateness.

Signature 12/3/17.

P.G. ASST.

AUNDIPATTI.

THENI (DT).

Name

Designation : P. G. Asst.

AUNDIPATTI.

Date : 12/3/17.

APPENDIX - IX

POVIDONE IODINE DRESSING PROCEDURE

POVIDONE IODINE DRESSING

Povidone iodine dressing is the nursing intervention using aseptic technique for the purpose of promoting healing and preventing infections given for 10 to 15 minutes by cleaning the diabetic foot ulcer with hydrogen peroxide, normal saline solution and application of povidone iodine impregnated dressing over the diabetic foot ulcer site.

OBJECTIVES OF POVIDONE IODINE DRESSING

1. To remove and dispose off of soiled dressing to prevent spread of infection
2. To cleanse area around the wound to prevent additional infection
3. To cleanse the wound area off puss and discharge
4. To apply sterile dressing to promote healing
5. To promote wound granulation
6. To promote thermal insulation to the wound surface
7. To provide for maintenance of high humidity between the wound and dressing
8. To promote physical, psychological and esthetic comfort

PRINCIPLES

1. Everything that comes in contact with a wound must be sterilized in the most effective way.
2. Hands must be thoroughly washed when handling equipment before dressing the wound
3. When cleaning a wound, clean from the least contaminated area to more contaminated area.

ARTICLES

S.NO	ARTICLES	RATIONALE
A STERILE TRAY CONTAINING		
1.	Gauze pieces	To clean the diabetic foot ulcer
2.	Sterile bowel	To keep the gauze piece To pour the dressing solutions
3.	K-basin	To receive the waste
4.	Artery Forceps	To hold the gauze piece by cleaning the wound
5.	Non-toothed thumb forceps	To squeeze the excess solution
6.	Gamgee Pads	To cover the wound after the dressing
7.	Sterile roller bandage	To provide compression dressing over the ulcer site
A CLEAN TRAY CONTAINING		
8.	0.5 % povidone iodine solution	To provide diabetic foot ulcer dressing
9.	0.9% Sterile saline	To clean the wound
10.	Hydrogen peroxide solution	To remove the debris from the diabetic foot ulcer
11.	Adhesive or non-allergic tape	To secure the dressing
12.	Scissors	To cut the roller bandage and adhesive tape
13.	Sterile gloves (1 pair)	To prevent infection
14.	Clean glove	To remove the soiled dressing
15.	Plastic bag for waste disposal	To receive the waste
16.	Towel	To prevent soiling of patient dress and linen
17.	Mackintosh	To prevent soiling of patient dress and linen
18.	Kidney tray	To receive the waste
19.	Cheatle forceps	To take the sterile articles

PRELIMINARY ASSESSMENT

- Level of consciousness and understanding of the patient
- Vital signs
- Allergy to tape or cleaning solutions
- Bleeding tendencies
- Bleeding or drainage from wound site
- Condition of the wound

PREPARATION OF THE PATIENT AND WARD

- Ensure that sweeping and mopping of ward is completed
- Explain procedure to the patient
- All articles should be assemble at patient bed side
- Proper lighting of the ward
- Switch off fan
- Provide privacy by using screens
- Fix disposable plastic bags in holders on the trolley. Place within reach for disposal of soiled dressing.

PROCEDURE

S. NO	NURSING ACTION	RATIONALE
1	Position the patient.	To comfort the patient
2	Explain the procedure to the patient. Screen the patient.	to improve the cooperation for the procedure
3	Instruct not to touch wound, equipment or dressing. Expose the dressing site.	To prevent contamination of the wound
4	Wash hands	To prevent transmission of infection
5	Open the sterile dressing, transfer gauze pieces into the dressing pack .	Make ready for the dressing.
6	Pour hydrogen peroxide solution into the dressing cup	For cleaning the wound
7	Place dressing mackintosh and towel under the part and place clean K-basin over mackintosh	Prevent soiling of the bed and linen.
8	Remove outer dressing	old dressing is contaminated
9	Do surgical hand washing	To prevent the transmission of the infection
10	Wear sterile gloves	To prevent infection
11	Flip open the dressing pack cover by inserting fingers in the inner layer of the wrapper	To make ready for the dressing.
12	Using thump forceps pick up gauze piece and wet it in hydrogen peroxide solution.	To clean the wound
13	Using artery clamp and thump forceps, squeezing the gauze	Prevent soiling and spillage of the solution
14	Clean the foot ulcer with hydrogen peroxide solution, using the same artery clamp, remove the gauze and dispose in the plastic bag	To remove the debris and death tissues from the wound

15	Discard the artery clamp	To prevent contamination
16	Using thump forceps pick up gauze piece and wet it in normal saline solution	To clean the wound
17	Using artery clamp and thump forceps, squeezing the gauze	Prevent soiling and spillage of the solution
18	Clean the foot ulcer with normal saline solution, using the same artery clamp, remove the gauze and dispose in the K- basin.	For cleansing purpose.
19	Observe the character and assess the condition of the wound	To assess the characteristic and condition of the wound
20	Use only thump forceps to pick up gauze piece.	To prevent contamination of the dressing materials.
21	Pick up gauze piece every time using only the thump forceps and soak in cleaning solution	To prevent contamination of the dressing materials.
22	Squeeze out excess solution from the gauze piece into the kidney basin (sterile)	Prevent soiling and spillage of the solution
23	Clean the wound (clean to dirty) with firm stroke using the artery clamp	To prevent contamination of the wound
24	Discard used gauze piece into the clean K-basin	To maintain cleanliness
25	Use only one gauze piece for each stroke	To prevent infection
26	Ensure wound is thoroughly cleaned	To maintain cleanliness of the wound
27	Finally, clean the skin in proximity to the wound edge, with strokes away from the wound	To prevent the transmission of the infection

28	Soak gauze piece in the povidone iodine solution, squeeze out excess solution, spread it keeping it over the sterile field	To prevent infection and improve wound healing
29	Apply over the wound, fully covering the wound with povidone iodine gauze pieces	To prevent infection and improve wound healing
30	Apply dry gauze pieces over the povidone iodine gauze pieces	To prevent dislodgement of the povidone iodine soaked gauze.
31	Apply pad over the wound and cover it with roller gauze.	To secure the dressing
32	Discard gloves	To prevent contamination
33	Discard the used artery clamp and thumb forceps into the clean K-basin	To prevent spread of infection
34	Secure dressing with adhesive/bandage	To keep the dressing in position
35	Position the patient in comfortable position.	To make the patient comfortable
36	Replace all the articles after discarding the waste.	Prevent transfer of micro organism
37	Record date, time, solution used, condition of the wound and any abnormalities.	To have proper documentation

APPENDIX – X

NORMAL SALINE DRESSING PROCEDURE

NORMAL SALINE DRESSING

Normal Saline dressing is the nursing intervention using aseptic technique for the purpose of promoting healing and preventing infections given for 10 to 15 minutes by cleaning the diabetic foot ulcer with hydrogen peroxide, normal saline solution and application of Normal Saline impregnated dressing over the diabetic foot ulcer site.

OBJECTIVES OF NORMAL SALINE DRESSING

1. To remove and dispose off of soiled dressing to prevent spread of infection
2. To cleanse area around the wound to prevent additional infection
3. To cleanse the wound area off puss and discharge
4. To apply sterile dressing to promote healing
5. To promote wound granulation
6. To promote thermal insulation to the wound surface
7. To provide for maintenance of high humidity between the wound and dressing
8. To promote physical, psychological and esthetic comfort

PRINCIPLES

1. Everything that comes in contact with a wound must be sterilized in the most effective way.
2. Hands must be thoroughly washed when handling equipment before dressing the wound
3. When cleaning a wound, clean from the least contaminated area to more contaminated area.

ARTICLES

S.NO	ARTICLES	RATIONALE
A STERILE TRAY CONTAINING		
1.	Gauze pieces	To clean the diabetic foot ulcer
2.	Sterile bowel	To keep the gauze piece To pour the dressing solutions
3.	K-basin	To receive the waste
4.	Artery Forceps	To hold the gauze piece by cleaning the wound
5.	Non-toothed thumb forceps	To squeeze the excess solution
6.	Gamgee Pads	To cover the wound after the dressing
7.	Sterile roller bandage	To provide compression dressing over the ulcer site
A CLEAN TRAY CONTAINING		
8.	0.9 % Normal Saline solution	To provide diabetic foot ulcer dressing
9.	Hydrogen peroxide solution	To remove the debris from the diabetic foot ulcer
10.	Adhesive or non-allergic tape	To secure the dressing
11.	Scissors	To cut the roller bandage and adhesive tape
12.	Sterile gloves (1 pair)	To prevent infection
13.	Clean glove	To remove the soiled dressing
14.	Plastic bag for waste disposal	To receive the waste
15.	Towel	To prevent soiling of patient dress and linen
16.	Mackintosh	To prevent soiling of patient dress and linen
17.	Kidney tray	To receive the waste
18.	Cheatle forceps	To take the sterile articles

PRELIMINARY ASSESSMENT

- Level of consciousness and understanding of the patient
- Vital signs
- Allergy to tape or cleaning solutions
- Bleeding tendencies
- Bleeding or drainage from wound site
- Condition of the wound

PREPARATION OF THE PATIENT AND WARD

- Ensure that sweeping and mopping of ward is completed
- Explain procedure to the patient
- All articles should be assemble at patient bed side
- Proper lighting of the ward
- Switch off fan
- Provide privacy by using screens
- Fix disposable plastic bags in holders on the trolley. Place within reach for disposal of soiled dressing.

PROCEDURE

S. NO	NURSING ACTION	RATIONALE
1	Position the patient.	To comfort the patient
2	Explain the procedure to the patient. Screen the patient.	to improve the cooperation for the procedure
3	Instruct not to touch wound, equipment or dressing. Expose the dressing site.	To prevent contamination of the wound
4	Wash hands	To prevent transmission of infection
5	Open the sterile dressing, transfer gauze pieces into the dressing pack .	Make ready for the dressing.
6	Pour hydrogen peroxide solution into the dressing cup	For cleaning the wound
7	Place dressing mackintosh and towel under the part and place clean K-basin over mackintosh	Prevent soiling of the bed and linen.
8	Remove outer dressing	old dressing is contaminated
9	Do surgical hand washing	To prevent the transmission of the infection
10	Wear sterile gloves	To prevent infection
11	Flip open the dressing pack cover by inserting fingers in the inner layer of the wrapper	To make ready for the dressing.
12	Using thump forceps pick up gauze piece and wet it in hydrogen peroxide solution.	To clean the wound
13	Using artery clamp and thump forceps, squeezing the gauze	Prevent soiling and spillage of the solution
14	Clean the foot ulcer with hydrogen peroxide solution, using the same artery clamp, remove the gauze and dispose in the plastic bag	To remove the debris and death tissues from the wound
15	Discard the artery clamp	To prevent contamination

16	Using thump forceps pick up gauze piece and wet it in normal saline solution	To clean the wound
17	Using artery clamp and thump forceps, squeezing the gauze	Prevent soiling and spillage of the solution
18	Clean the foot ulcer with normal saline solution, using the same artery clamp, remove the gauze and dispose in the K-basin.	For cleansing purpose.
19	Observe the character and assess the condition of the wound	To assess the characteristic and condition of the wound
20	Use only thump forceps to pick up gauze piece.	To prevent contamination of the dressing materials.
21	Pick up gauze piece every time using only the thump forceps and soak in cleaning solution	To prevent contamination of the dressing materials.
22	Squeeze out excess solution from the gauze piece into the kidney basin (sterile)	Prevent soiling and spillage of the solution
23	Clean the wound (clean to dirty) with firm stroke using the artery clamp	To prevent contamination of the wound
24	Discard used gauze piece into the clean K-basin	To maintain cleanliness
25	Use only one gauze piece for each stroke	To prevent infection
26	Ensure wound is thoroughly cleaned	To maintain cleanliness of the wound
27	Finally, clean the skin in proximity to the wound edge, with strokes away from the wound	To prevent the transmission of the infection
28	Soak gauze piece in the normal saline solution, squeeze out excess solution, spread it keeping it over the sterile field	To prevent infection and improve wound healing

29	Apply over the wound, fully covering the wound with Normal saline gauze pieces	To prevent infection and improve wound healing
30	Apply dry gauze pieces over the povidone iodine gauze pieces	To prevent dislodgement of the Normal saline soaked gauze.
31	Apply pad over the wound and cover it with roller gauze.	To secure the dressing
32	Discard gloves	To prevent contamination
33	Discard the used artery clamp and thumb forceps into the clean K-basin	To prevent spread of infection
34	Secure dressing with adhesive/bandage	To keep the dressing in position
35	Position the patient in comfortable position.	To make the patient comfortable
36	Replace all the articles after discarding the waste.	Prevent transfer of micro organism
37	Record date, time, solution used, condition of the wound and any abnormalities.	To have proper documentation

APPENDIX – XI

PHOTOGRAPHS

Investigator Collecting the Data

Investigator doing the dressing